

Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Sharon F. Kleyne	: :	Group Art Unit: 1617
Serial No. 09/614,790	:	Examiner: Shengjun Wang
Filed: July 12, 2000	:	Tel. No. (571) 272-0632
For a Patent for METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	Date: April 7, 2006

APPELLANT'S BRIEF UNDER PART 41 OF TITLE 37 C.F.R.

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

This brief is in furtherance of the Notice of Appeal, filed on February 27, 2006. Pursuant to 37 C.F.R. §41.20(b)(2), a check for $250, the small entity fee for filing the Appeal Brief, is enclosed herewith.

Ths brief contains the following items under the following headings, and in the order set forth below, according to 37 C.F.R. §41.37, each item beginning on a separate sheet.

I. Real Party in Interest

II. Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

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V. Summary of Claimed Subject Matter

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The final page of this brief bears the signature of the Attorney for Appellant and a Certificate of Mailing.

I. Real Party in Interest

The real party in interest in this appeal is the party named in the caption of this brief.

II. Related Appeals and Interferences

With respect to other appeals, interferences, or judicial proceedings that are related to, will directly affect, will be directly affected by, or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences.

III. Status of Claims

The status of the claims in this application is as follows.

Claims in the application are 1 to 101. Claims 1 to 89 have been cancelled. Claims 94-96 are withdrawn from consideration. Claims 90 to 93 and claims 97 to 101 are pending and have been twice rejected. The claims on appeal are claims 90 to 93 and 97 to 101.

IV. Status of Amendments

No Amendments have been filed subsequent to the final rejection dated November 30, 2005.

V. Summary of Claimed Subject Matter

Appellant's invention is a method for moisturizing the eye. Appellant's method for moisturizing the eye is by spraying a mist (specification, page 4, lines 21-22) of small droplets (specification, page 6, line 14) consisting essentially of water (specification, page 7, lines 1-3) to the surface of the eye in an amount that is sufficient to hydrate the aqueous layer of the tear film but is below that which will wash away the tear film (specification, page 4, lines 8-10). The water mist is sprayed onto the surface of the eye from a device comprising a sealed container (specification, page 8, line 32) and an actuator that delivers a mist (specification, page 8, line 16), and the mist is sprayed within a period of 10 seconds (specification, page 4, line 18).

The method of the invention is a significant advance over the prior art because, unlike the prior art, it results in the rehydration of the aqueous layer of the tear film while retaining the integrity of the normal trilaminar structure of the tear film. See, the specification, page 4, lines 6 to 10, and page 10, line 12-17. Application by a mist in accordance with the invention provides optimal hydration of the tear film and moisturization of the surface of the eye. See, the specification, page 4, lines 21-26. In accordance with the invention, applying a volume of fluid by a mist results in a sudden increase in humidity to the tear film. This is in direct contrast to present day methods of moisturizing the eye in which a quantity of a hydrating fluid, typically in the form of a drop, a stream, or a jet of drops, is administered to the surface of the eye, which provides a splash of water that washes away the tear film and replaces it with the hydrating fluid. See, the specification, page 2, line 26, to page 3, line 2, and page 10, lines 5 to 11.

The method of the invention provides another significant advance over the prior art as it utilizes a sprayed mist of water, rather than of a moistening liquid, comfort liquid, eye drop liquid,

or liquid medium as practiced in the prior art. This permits the method of the invention to replace water that has been lost from the aqueous layer of the tear film, rather than substituting the aqueous layer of the tear film with some undefined, foreign liquid that must then be removed from the surface of the eye by the blinking process. Thus, unlike the prior art, the method of the invention provides a sudden increase in humidity to the tear film and does not replace the tear film with a foreign liquid. See, the specification, page 5, lines 10-14, and lines 30-35.

Support for all limitations of the claims is contained in the above cited portions of the specification.

VI. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed on appeal is a rejection of claims 90 to 93 and 97 to 101 as being obvious under 35 U.S.C. §103(a) over the combined disclosures of Junkel, U.S. Patent No. 5,620,633; Hahn, U.S. Patent No. 5,893,515; Hutson, U.S. Patent No. 5,588,564; and Embleton, WO 97/23177.

VII. Argument

The presently claimed invention is not obvious in view of the prior art

Appellant submits that claims 90 to 93, 97, and 101 are grouped together but that these claims are not grouped with claims 98 to 100, for reasons that are discussed below.

A. The Examiner has failed to make a prima facie case for obviousness of the claims

The primary reference cited by the Examiner, Junkel, U.S. Patent No. 5,620,633, discloses a portable misting device for sunbathers and others involved in athletic pursuits. The device provides a cooling air current with an atomized liquid mist, such as water, and directs the cooling air current in a direction set by a user. The device of Junkel, because it is meant to "combat the elements of heat and dehydration attendant with athletic activities and/or prolonged exposure to the sun" (see column 1, lines 15-19), is presumably meant to be used by directing such moist air current into an area occupied by a sunbather or one engaged in athletic pursuits or directly onto the surface of the body of such individual.

Junkel does not disclose moisturizing the surface of the eye, but rather pertains to cooling the body of one suffering from heat or dehydration due to sun exposure or sweating due to athletic endeavors. The Examiner has stated, in the Office Action mailed on March 17, 2005 and in the present Office Action, that Junkel does not disclose applying the mist to the face or to a subject in need of moisturizing the eye. Accordingly, Appellant submits that the primary Junkel reference is not pertinent whatsoever to the present invention.

The secondary references cited by the Examiner, when combined with Junkel, do not disclose or suggest the present invention.

Hahn, U.S. Patent No. 5,893,515, discloses an apparatus for generating a mist of a liquid medium. See column 4, line 45. The mist may be directed to the eye or to the skin surface. See, column 4, line 54. When used with the eye, "each pump actuation will provide a sufficient amount of comfort liquid or drug to saturate the eye without overflowing - about one drop." See column 12, lines 10-14.

It is noted that Hahn does not disclose administering "water" to the surface of the eye. Rather, Hahn refers to liquid medium (column 4, line 45), liquids (column 7, line 36), comfort liquids (column 12, line 12), or eye drop liquids (column 13, line 54). Appellant has previously submitted two Declarations, one by Dr. Rachael Garrett on January 9, 2002 (see Evidence Appendix IX, No. 1), who testified that "Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects", and one by Dr. Philip Paden on January 21, 2004 (see Evidence Appendix IX, No. 2), who testified that the use of water as a moisturizing agent for the eye represents a significant departure from previously accepted doctrines in the field of ophthalmology. Thus, it is submitted that Hahn does not disclose or suggest the administration of water to the surface of the eye, as is called for in the present claims.

Additionally, Hahn discloses that the amount of the liquid, liquid medium, comfort liquid, or eye drop liquid that is to be administered to the eye is "a sufficient amount of comfort liquid or drug to saturate the eye without overflowing - about one drop." Appellant submits that this is a teaching away from the present invention, which calls for an amount that will not wash away the tear film of the eye. As disclosed in the present specification on page 2, a drop has a volume of about 20 to 25 μl which is sufficient to flood the eye and to wash away the tear film and replace it

with whatever is in the fluid that comprises the drop. This flooding of the eye with the washing away the tear film occurs even without overflowing the eye. Thus, the volume prescribed by Hahn is in direct contrast to that called for in the present claims.

Pending claims 98 to 100 further distinguish over this teaching of Hahn and so provide additional features to support patentability over the prior art. Hahn discloses that one drop should be administered and, as disclosed in the present specification, one drop contains between 20 and 25 μl (microliters). Claims 98 to 100 call for less than 10 μl, between about 0.5 and 6 μl, and between about 2 and 5 μl, respectively. Thus, these claims provide further clear distinctions over the prior art and Appellant submits that these claims should be considered separately and not within the same group as the other pending claims.

Hutson, U.S. Patent No. 5,588,564, discloses an apparatus for providing a mist of a liquid to the surface of the eye. Hutson, like Hahn, does not disclose the administration of water as a moisturizing agent for the surface of the eye. Rather, Hutson discloses the delivery of "a fluid" (Abstract, and column 2, line 6), an "eye wash solution" (column 1, line 51), or "an eye solution mist" (column 1, line 65). Additionally, Hutson is silent as to the volume of liquid that is dispensed to the eye.

Embleton, WO 97/23177, is concerned with a different problem than that of the present invention. The present invention deals with the problem of moisturizing the eye. Embleton deals with and provides a solution to the problem of over-administering a treatment fluid to the surface of the eye. Such over-administering results in two deleterious effects. The first such deleterious effect is that providing a medicament in an amount of liquid that is greater than that which can be retained by the eye results in wastage of the medicament due to runoff from the eye and also

results in a lack of precision in dosage because one does not know how much of the over-administered medicament was actually retained in the eye. The second and more serious deleterious defect of over-administration to the eye is that providing a medicament in too large of a volume of fluid to the eye results in drainage of the medicament down the tear duct and into the nasal passages from where it can be inhaled into the systemic circulation of a patient, with potentially disastrous effects depending on the nature of the medicament. As a solution to this problem, Embleton discloses an apparatus that targets a treatment liquid in the form of a jet or a stream to the surface of the eye and which delivers a small volume of a treatment fluid so as not to flood the eye.

Embleton teaches away from the present invention which calls for spraying a mist as Embleton discloses the necessity of administering the fluid as a jet or stream. With the Amendment filed on July 9, 2001, Appellant submitted page 1231 of the Random House Dictionary of the English Language (1987) (see Evidence Appendix IX, No. 3). The term "mist" is defined as:

> **1.** a cloudlike aggregation of minute globules of water suspended in the atmosphere at or near the earth's surface, reducing visibility to a lesser degree than fog. **2.** a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief. . .* (emphasis in the original)

The Examiner previously stated that there is no difference between the mist of the invention and the jet or stream of Embleton. As stated by the Examiner on page 6 of the Office Action of October 4, 2004:

> The Examiner fails to see the difference between the "mist" and the stream of droplets disclosed by Embleton. They are both a mass of droplets *dispersed* in air. (emphasis added)

With the Amendment filed on December 9, 2004, Appellant submitted page 406 of Webster's New World Dictionary of the American Language, Second College Edition, Simon and Schuster (1980)(see Evidence Appendix IX, No. 4). The term "disperse" is defined as follows:

> dis·perse *vt.* -persed', -pers'ing . . . 1. to break up and scatter in all directions; spread about; distribute widely 2. to dispel (mist, etc.) 3. to break up (light) into its component colored rays - *vi.* to break up and move in different directions; scatter - ***SYN.*** see SCATTER . . .

Embleton specifically teaches that the fluid cannot be administered as a dispersed mass of droplets. Embleton discloses, on page 3, lines 6 to 9 that:

> The jet or stream can be directed or targeted at a chosen site in an eye; eg, cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva, or palpebral conjunctive . . .

It is evident that administration of a fluid by any method that provides for dispersed droplets cannot be targeted to the eye, much less to a chosen site in an eye. Therefore, it is clear that Embleton teaches away from dispersed droplets in air, which would be a mist and not a jet or stream, as required by Embleton.

Further, Embleton does not disclose the administration of water to the eye. On page 13, lines 6 to 12, Embleton discloses that the ophthalmic treatment liquids that may be used with the jet or stream delivery device of the invention include:

> 6) Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds such as acetylcysteine, hydroxyethylcellulose, hydroxymellose, hyaluronic acid, polyvinyl alcohol, polyacrylic acid derivatives, etc.

As argued by Appellant, and as testified by Dr. Rachael Garrett in her Declaration filed on December 18, 2001 (see Evidence Appendix IX, No. 1), the disclosure of Embleton would not be

construed by one skilled in the art as referring to the administration of water, but rather to administration of a treatment fluid based on water. Just as one skilled in the art would not construe the disclosure of Embleton to refer to the administration of oils into the eye but rather would understand this disclosure to mean an oil-based (lipophilic) eye therapy, comfort drop, or irrigation fluid, one skilled in the art would understand the disclosure of water to mean a water-based (aqueous) eye therapy, comfort drop, or irrigation fluid. Dr. Philip Paden, in his Declaration filed on January 21, 2004 (see Evidence Appendix IX, No. 2), testified that the use of water as a moisturizing agent for the eye represents a significant departure from previously accepted doctrines in the field of ophthalmology.

Because the prior art does not disclose or suggest the administration of a fluid consisting essentially of water to moisturize the eye, does not suggest the administration of any fluid to moisturize the eye, including water, in an amount that is less than that which will wash away the tear film, or of spraying this amount of water onto the eye in the form of a mist in order to moisturize the eye, Appellant submits that the Examiner has failed to make a prima facie case that the presently claimed invention is obvious in view of the prior art.

B. Even if a prima facie case of obviousness has been made, Appellant has submitted sufficient evidence to rebut the rejection

Appellant submits that, even if it is determined that the prior art cited by the Examiner is sufficient to establish prima facie obviousness of the claimed invention, Appellant has overcome this basis of rejection by the submission of numerous Declarations. The Examiner's attention is brought to the following previously submitted Declarations and other submissions.

1. Appellant has submitted, on January 30, 2004, a Declaration by Dr. Philip Paden who testified that the present invention is a departure from previous accepted doctrine in ophthalmology. This Declaration is submitted herewith in Evidence Appendix IX, No. 2. Submitted with this Declaration on January 30, 2004 was a 3-minute long CD disc entitled "Bio-Logic Aqua Technologies" that diagrammatically shows how the invention, when practiced by application of a mist, restores the osmolarity of a tear film in a person suffering from dry eye to a comfortable physiologic level, and how such a mist may be used to moisten the eye using water, in contrast to previously accepted ophthalmologic dogma. This CD is submitted herewith in Evidence Appendix IX, No. 2A.

Dr. Paden, in his Declaration, testified that it has been a long-accepted doctrine in the field of ophthalmology that administration of water to the eye is not a suitable therapy because of the reduction of osmolarity on the surface of the eye with resultant deleterious effects. The present invention overcomes this problem by administering the water in the form of tiny droplets which do not wash away the tear film but rather become incorporated into it. Thus, there is no decrease below normal osmolarity and no resultant deleterious effects. This incorporation of the droplets into the tear film is graphically shown in the CD of Evidence Appendix, No. 2A and it is respectfully requested that the Board view this very brief CD to obtain a more complete understanding of the invention and how it overcomes problems of prior art methods of eye moisturization.

2. Appellant has submitted, on January 30, 2004, a Declaration by Dr. William Mathers who testified regarding unexpected advantageous properties obtained by the method of the invention. This Declaration is submitted herewith in Evidence Appendix IX, No. 5.

In this Declaration, Dr. Mathers testified that he ran a study to evaluate patient response to treating symptoms of dry eye or other ocular irritation with a commercial embodiment of the present invention compared with the previous treatments that these patients had used for their symptoms. As testified by Dr. Mathers, even though 72% of the patients surveyed had experienced favorable results with their previous treatments, 72% of the patients stated that the commercial embodiment of the invention was more effective than their previous treatment and 83% of the patients stated that it was more convenient to use than their previous treatment. 83% of the patients said that they would buy the commercial embodiment of the present invention.

Appellant submits that this Declaration establishes unexpected advantageous properties of the present invention as it was shown that, even in patients who had good results with other methods for moisturizing the eye, patients found the present invention to be more convenient to use and more effective.

3. Appellant has submitted, on January 30, 2004, a Declaration by Dr. Darwin Liao who testified regarding unexpected advantageous properties obtained by the method of the invention. This Declaration is submitted herewith in Evidence Appendix IX, No. 6.

Dr. Liao is an ophthalmologist who testified that the use of a commercial embodiment of the invention has eliminated problems that he previously encountered with patient compliance in the use of therapies for treating symptoms of dry eye. Dr. Liao also testified that the commercial embodiment of the invention overcomes problems that many people, such as elderly people with motor difficulties, have in administering prior art dry eye therapies. Appellant submits that this Declaration is evidence of further unexpected advantageous properties of the invention.

4. Appellant has submitted, on May 10, 2005, a Second Declaration by Dr. William Mathers who testified the invention addresses and solves a long-standing unresolved problem pertaining to the treatment of patients with symptoms due to dry eyes. This Declaration, with its attachments, is submitted herewith in Evidence Appendix IX, No. 7.

In this Declaration, Dr. Mathers testified that the problem of patient compliance with dry eye therapies, such as eye drops, has long been a problem in ophthalmology and that there has not been found a solution to this long-standing problem. Dr. Mathers further testified that the use of the eye mist of the invention increases patient compliance regarding the use of eye moisturizes and that the present invention provides a solution to the longstanding problem of lack of patient compliance with eye moisturizing products.

5. Appellant also has submitted, with the Amendment filed on January 30, 2004, an article in Exchange & Commissary News, 43(1):6 (January 15, 2004). This article is submitted herewith in Evidence Appendix IX, No. 8. This article discloses that the U.S. military is using a commercial version of the invention and is supplying it to troops in Iraq who have found it to be superior to other products in moisturizing their eyes in that harsh desert climate. This establishes the commercial success of the invention and acceptance of the product embodying the invention by the marketplace.

Appellant submits, accordingly, that even if the prior art establishes prima facie obviousness of the invention, the declaratory and other evidence submitted by Appellant is sufficient to overcome such prima facie obviousness.

Conclusion

Appellant submits that, for the reasons discussed above, the Examiner has failed to establish prima facie obviousness of the claims. Appellant further submits that, if the Board finds that the Examiner has established prima facie obviousness of the claims, the evidence submitted by Appellant in the form of declarations and publication, is sufficient to overcome the prima facie obviousness. It is submitted that Appellant has established that the claims are patentably distinct from the prior art and the Board is requested to rule accordingly.

VIII. Claims Appendix

Claims 1 to 89 (canceled)

90. A method for moisturizing the eye comprising spraying a mist consisting essentially of droplets of water having an average diameter between 5 and 150 microns on the surface of the eye of a subject in need thereof, wherein the amount of water that is sprayed on the eye is sufficient to hydrate the aqueous layer of the tear film on the eye of the subject but is below that which will wash away the tear film, and wherein the mist is sprayed from a device comprising a sealed container, water within said container, and an actuator for spraying a mist of water from said container, and wherein the water is sprayed on the surface of the eye within a period of 10 seconds.

91. The method of claim 90 wherein the subject is suffering from dry eye.

92. The method of claim 90 wherein proteins and electrolytes that were present in the tear film on the surface of the eye prior to the delivery of the aqueous fluid are present in the tear film following the delivery of the aqueous fluid to the surface of the eye as determined by high performance liquid chromatography (HPLC).

93. The method of claim 90 wherein the device further comprises a sealed flexible pouch containing said water within said container and a pressurization agent between said container and said pouch.

94 to 96. (withdrawn)

97. The method of claim 90 wherein the water is sprayed within a period of 5 seconds.

98. The method of claim 90 wherein less than about 10 μl is sprayed onto the surface of the eye.

99. The method of claim 90 wherein between about 0.5 and 6 μl is sprayed onto the surface of the eye.

100. The method of claim 90 wherein between about 2 and 5 μl is sprayed onto the surface of the eye.

101. The method of claim 90 wherein the subject is suffering from dryness of the eye.

IX. Evidence Appendix

The following copies of evidence previously submitted in the prosecution of this application and previously entered by the Examiner is submitted herewith.

No. 1. - Declaration of Dr. Rachael Garrett, filed with Amendment of January 9, 2002

No. 2. - Declaration of Dr. Philip Paden, filed with Amendment of January 21, 2004

No. 2A - CD disc entitled "Bio-Logic Aqua Technologies", submitted as an attachment to Declaration of Dr. Philip Paden, filed with Amendment of January 21, 2004

No. 3 - Random House Dictionary of the English Language, page 1231(1987), submitted with Amendment of July 9, 2001

No. 4 - Webster's New World Dictionary of the American Language, Second College Edition, Simon and Schuster, page 406 (1980), submitted with Amendment of December 9, 2004

No. 5 - Declaration of Dr. William Mathers, filed with Amendment of January 30, 2004

No. 6 - Declaration of Dr. Darwing Liao, filed with Amendment of January 30, 2004

No. 7 - Second Declaration of Dr. William Mathers, submitted on May 10, 2005

No. 8 - Exchange & Commissary News, 43(1):6 (January 15, 2004), submitted with Amendment of January 30, 2004

X. Related Proceedings Appendix

Not applicable

CONCLUSION

For the foregoing reasons, Appellant submits that the Examiner's rejection of claims 90 to 93 and 97 to 101 was erroneous and requests that the rejection of the claims be reversed.

Respectfully submitted,



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Perkasie, PA 18944
(215) 453-9237
Attorney for Appellant

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 7, 2006.

Dated: 4/7/2006



Howard M. Eisenberg

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PATENT APPLICATION EXAMINING OPERATIONS

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In re the Application of
Sharon F. Kleyne

Serial No. 09/614,790

Filed: July 12, 2000

For a Patent for
METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE

Group Art Unit: 1619

Examiner: Michael Willis

Tel. No. (703) 305-1679

FIRST DECLARATION OF DR. RACHAEL GARRETT
37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir,

1. I, Rachael Garrett, OD, am a clinical optometrist working at the Oregon Health Sciences University. My resume is attached hereto. I am familiar with portions of the prosecution of this application.

2. I am submitting this Declaration in response to the contention of the Examiner that the Embleton reference, WO 97/23177, cited against the application discloses water as an ophthalmic treatment liquid.

3. Embleton discloses, on page 13, that ophthalmic treatment liquids that may be used in accordance with his invention include: "Artificial tear/dry eye therapies, comfort drops, irrigation fluids. etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds. . ."

4. Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects. These essential ingredients include (a) tonicity agents such as dextran 40 and 70, glycerin, potassium glycol, and sodium chloride, (b) viscosity increasing agents, such as carboxymethylcellulose, dextran 70, gelatin, glycerin, hydroxymethylcellulose, poloxamer 407, polysorbate 80, propylene glycol, polyvinyl alcohol, an polyvinylpyrrolidone, and (c) wetting agents, such as polysorbate 20 and 80, poloxamer 282, and tyloxapol. Additionally, these formulations usually, but not necessarily, contain (d) preservatives. such as benzalkonium chloride, cetylpyridinium, thimerosal, methyl/propyl paraben, sodium benzoate, sodium propionate, and sorbic acid, and (e) antioxidants, such as EDTA, sodium bisulfite, sodium metabisulfite, sodium thiosulfate, and thiourea.

5. Therefore, it is my understanding that Embleton does not disclose the use of water. per se. as an artificial tear/dry eye therapy or comfort drop. Rather. my understanding is that Embleton discloses artificial tear/dry eye therapies and comfort drops that are based upon saline. water or oil, and which include other ingredients that are necessarily present in these formulations

6. It is my opinion that most eye care professionals, other than myself, would also understand the disclosure of Embleton as I have stated above.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

12/18/01
Date

Rachael Garrett
Rachael Garrett, OD

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Curriculum Vitae

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Biographical Information: Date of Birth: September 25, 1970, West Covina, California
Spouse: Jeffrey H. Garrett

Education: Doctor of Optometry *"With Distinction"*
Southern California College of Optometry, Fullerton, California
May, 1997

Bachelor of Arts, Biological Sciences
Hanover College, Hanover, Indiana
January, 1993

Specialty Certification: Optometric Residency, Hospital based/Primary care, Geriatric Optometry
Sepulveda Veterans Affairs Medical Center, Sepulveda, California
July, 1998

Professional Licensure: State of California, 10933T (diagnostic and therapeutic certification)
State of Oregon, 2713T (diagnostic and therapeutic certification)

Clinical/ Optometric Experiences:

Optometrist, Casey Eye Institute, Oregon Health Sciences University, Portland, Oregon, February, 1999-present

Optometrist, Laser Eye Center, Ontario, California, July, 1998-January, 1999

Clinical Instructor, Cornea and Contact Lens Service, Optometric Center of Fullerton, Fullerton, California, August, 1997-July, 1998

Optometric Resident, Sepulveda Veterans Affairs Medical Center, Sepulveda, California, July, 1997-July, 1998

Optometric Intern, Optometric Center of Fullerton, Fullerton, California, July, 1995-May, 1996 and February, 1997-May, 1997

Optometric Intern, Developmental Optometry Group, Newport, California, November, 1996-February, 1997

Optometric Intern, Optometric Center of Los Angeles, Los Angeles, California, August, 1996-November, 1996

Optometric Intern, Santa Barbara Veterans Affairs Outpatient Clinic, Santa Barbara, California, May, 1996-August, 1996.

Tutor, Treatment and Management of Ocular Disease Southern California College of Optometry, Fullerton, California, January, 1997-May, 1997

Teaching Assistant for Dr. John Nishimoto, Ocular Disease Case Analysis. Southern California College of Optometry, Fullerton, California. March, 1997-May, 1997

Teaching Assistant, Arizona Optometric Association, Continuing Education Courses, Phoenix, Arizona, June, 1996

Teaching Assistant for Dr. David Kirschen, Binocular Vision and Sensory Perception. Southern California College of Optometry, Fullerton, California. February, 1996-May, 1996

Teaching Assistant for Dr. John Nishimoto, Introduction to Optometric Case Analysis, Southern California College of Optometry. Fullerton, California. November, 1995-February, 1996

Appointments:

President, Portland Metropolitan Optometric Society, 2001-Present

Member, Third Party Committee, Oregon Optometric Physicians Association, 2001- Present

Board of Directors, Portland Metropolitan Optometric Society, 1999-Present

Adjunct Assistant Professor, Pacific University College of Optometry, Forest Grove, OR, 1999-Present

Director, Comanagement Services, Casey Eye Institute, Vision Correction Center. 1999-Present

Membership Development Task Force, American Academy of Optometry. 1997-1998

Class of 1997 Chair, Young Alumni Committee, Southern California College of Optometry, 1997-1998

American Optometric Student Association National Student Liaison to the American Academy of Optometry, 1996-1997

Curriculum Committee, Southern California College of Optometry, 1996-1997

Editor. Study Guide for the National Board of Examiners in Optometry. Southern California College of Optometry. 1995-1996

SCCO Student Liaison to the American Academy of Optometry. 1994-1996

Professional Organizations:

Oregon Optometric Physicians' Association, 1999- Present

American Academy of Optometry, Fellow. 2000- Present

American Optometric Student Association/ American Optometric Association, 1993- Present

American Academy of Optometry Student Member, 1994-1998

Beta Sigma Kappa International Optometric Honor Society. 1994-1997

American Public Health Association, 1994-1995

Research:

Garrett RL, Rich LF, Mathers WD. 2001. Measurement of Flap Thickness with Confocal Microscopy (in process). Garrett RL. 2001. Posterior Corneal Changes Post LASIK (in process).

Mathers WD, Waikom, B, Garrett, RL. 2000. The Effects of Laser in situ keratomileusis on tear film and corneal sensitivity (in process).

Garrett, RL, Housman, CL, Schornack, JA. 1996. The Effects of Multivitamins and Topical Vitamin A on the Tear Film of Presbyopic Soft Contact Lens Wearers. Senior Research Project, Southern California College of Optometry.

Presentations:

Herpes Simplex Keratitis Post-LASIK, Refractive Surgery Case Conference. Casey Eye Institute, Portland, OR 2001

Posterior Corneal Changes Following LASIK, Vision 2001, Casey Eye Institute, Portland, OR 2001.

Cornea and Refractive Surgery Update, Optometric Continuing Education Course, Casey Eye Institute, Portland, OR 2001.

Garrett, RL. Corneal Topography in Refractive Surgery. Class of 2002. Pacific University College of Optometry, Forest Grove, Oregon, 2001

Garrett, RL. Topography Pearls, Refractive Surgery Case Conference, Casey Eye Institute, Portland. OR 2001

Mathers. WD. Garrett. RL. Applications of Confocal Microscopy in Refractive Surgery, Portland Metropolitan Optometric Society Monthly Meeting, Casey Eye Institute. Portland. Oregon 2001

Garrett, RL. LASIK and Dry Eye, Oregon Ophthalmological Alumni Association- 55th Annual Alumni Meeting, Casey Eye Institute, Portland, Oregon 2000

Garrett, RL. Physical Optics, Resident's Lecture Series. Casey Eye Institute. Portland, Oregon, 2000

Garrett, RL. Geometrical Optics I, Resident's Lecture Series, Casey Eye Institute, Portland, Oregon. 2000

Garrett, RL. Geometrical Optics II. Resident's Lecture Series, Casey Eye Institute, Portland. Oregon. 2000

Presentations:
(Continued)

Garrett, RL. Clinical Refraction- Subjective Refraction, Resident's Lecture Series, Casey Eye Institute, Portland, Oregon, 2000

Garrett, RL. Preoperative Risks...Postoperative Realities, Continuing Optometric Education Course, Casey Eye Institute, Portland , Oregon, 2000

Garrett, RL, Rich LF. Updates in Refractive Surgery, Class of 2000, Pacific University College of Optometry, Forest Grove, Oregon, 2000

Garrett, RL. Optics of Excimer Lasers. Class of 2000, Pacific University College of Optometry, Forest Grove, Oregon, 2000

Garrett, RL. Pre and Postoperative Applications of Corneal Topography. Class of 2000, Pacific University College of Optometry, Forest Grove, Oregon, 2000

Garrett, RL. Treatment of Astigmatism with the Excimer Laser. Refactive Surgery Case Conference, Casey Eye Institute, Portland, Oregon 2000

Garrett, RL. Corneal Topography and the Vision Correction Patient. Cross Talk Faculty Education Series, Pacific University College of Optometry, Forest Grove, Oregon, 1999

Garrett, RL. Treatment of Central Islands. Refractive Surgery Case Conference, Casey Eye Institute, Portland, Oregon 1999

Garrett, R.L. Cornea and Refractive Surgery Update. Continuing Optometric Education Course, Casey Eye Institute, Portland , Oregon. 1999

Garrett, RL. Corneal Topography and the Excimer Laser Patient. Oregon Ophthalmological Alumni Association- 54th Annual Alumni Meeting, Casey Eye Institute, Portland, Oregon 1999

Garrett, R.L. Pre and Postoperative Care of the Excimer Laser Patient Columbia Gorge Seminar- Cataract, Cornea and Refractive Surgery Update, Casey Eye Institute, Portland , Oregon, 1999

Garrett, R.L. Innovative Changes in Refractive Surgery. Class of 1999, Pacific University College of Optometry, Forest Grove, Oregon, 1999

Garrett, RL. Conjunctival and Corneal Dysplasia, Carcinoma in situ and Invasive Squamous Cell Carcinoma. Poster Presentation, American Academy of Optometry, San Francisco, California, 1998

Presentations:
(Continued)

Garrett, RL. Conjunctival and Corneal Dysplasia, Carcinoma in situ and Invasive Squamous Cell Carcinoma. Continuing education course, Southern California College of Optometry, Fullerton, California, 1998

Garrett, RL. Conjunctival and Corneal Dysplasia, Carcinoma in situ and Invasive Squamous Cell Carcinoma. Fourth year student block lectures, Southern California College of Optometry, Fullerton, California, 1998

Garrett, RL, Housman, CL, Schornack, JA. The Effects of Multivitamins and Topical Vitamin A on the Tear Film of Presbyopic Soft Contact Lens Wearers. Poster Presentation, American Academy of Optometry, Orlando, Florida, 1996

Awards and Honors:

Hedda Jaanus Podrang Memorial Scholarship Fund, 1997

Dr.'s Robert L. Gordon & Andrea C. Silvers Award, 1997

Dr. Roy and Mrs. Lynn Smith Scholarship Award, 1996

Vision Service Plan Independent Practice Award, 1996

Wesley-Jessen Student Travel Fellowship Award, 1996

Beta Sigma Kappa Research Grant, 1996

Southwest Contact Lens Society Award, 1995

Bausch and Lomb Student Leadership Award, 1995

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Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Sharon F. Kleyne	: :	Group Art Unit: ~~1619~~ 1617
Serial No. 09/614,790	:	Examiner: Michael Willis
Filed: July 12, 2000	:	Tel. No. (703) 305-1679
For a Patent for METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	

DECLARATION OF DR. PHILIP PADEN
37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

1. I, Philip Y. Paden, MD, am a physician and surgeon (ophthalmology) and owner of Paden Eye Care Center, PC in Medford, Oregon. A copy of my curriculum vitae is attached hereto and forms a part of this declaration. I am a paid consultant to Rogue Valley Natural Springs, Inc., a company that commercializes an eye-moisturizing product described and claimed in the application. This company was founded by Sharon F. Kleyne, the inventor of the present application. I am also a shareholder in the company. I am familiar with the prosecution of this application in the U.S. Patent Office.

2. I am submitting this declaration to explain the significance of the disclosed and claimed method for moisturizing the surface of the eye using an aqueous fluid consisting essentially of water and to establish that such a use of water represents a significant departure from previous accepted doctrine in ophthalmology.

3. It is a well established physiological principle that all cells (oral and upper GI mucosa excepted) of the body, including cells on the surface of the eye, are bathed in a fluid having a particular osmolarity and that significant deviations from a narrow range of physiologic osmolarity of the fluid may have deleterious consequences for cells exposed to the fluid. Such consequences may be minor, such as temporary discomfort while the body re-establishes normal osmolarity, or such consequences may be severe, such as osmotic shock whereby exposure of cells to an extremely hypotonic environment results in rupture of the plasma membrane and loss of cell contents causing death of cells.

4. For this reason, it has been a long-recognized and accepted doctrine in ophthalmology that pure water, or an aqueous fluid consisting essentially of water, cannot be used as a topical eye therapy because application of water in the form of a drop, a jet, or a stream would decrease the osmolarity of fluid on the surface of the eye to almost zero and would result in deleterious effects such as stinging sensations or even osmotic shock with damage to cells on the surface of the eye.

5. The present application and the commercial embodiment of the claimed invention (Nature's Tears by Rogue Valley Natural Springs, Inc.) provide a solution to this problem and permit the application of essentially pure water to the surface of the eye. By administering a small quantity of water in the form of small droplets within a mist, water does not displace the tear film but rather is absorbed into the aqueous layer of the tear film. In this way, the hypertonic tear film in a patient suffering from dry eye is restored to within a comfortable physiologic range and there is no resultant irritation or other deleterious effects due to osmotic shock.

6. The way that the mist embodiment of the invention works is explained and illustrated in the accompanying CD disk that is submitted with this declaration as "Paden Exhibit 1." Paden Exhibit 1 is a 3-minute CD presentation produced by Rogue Valley Natural Springs, Inc. to explain their product, Nature's Tears™. This presentation diagrammatically shows how the application of water in the form of a mist restores the desired osmolarity of the tear film to a comfortable physiologic level and does not result in osmotic shock, in contrast to previously accepted ophthalmologic dogma. Maintenance of the lipid and mucin layers are further benefits not previously available in any other dry eye supplement.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1-21-2004
Date

Philip Paden
Philip Paden, MD

CURRICULUM VITAE

Philip York Paden, M.D.
221 Stewart Avenue, Suite 110
Medford, OR 97501
(541) 776-9026

EDUCATION:

July, 1983 – July 1986
Residency in Ophthalmology
Oregon Health Sciences University, Portland, Oregon

1982 – 1983
Internship in Internal Medicine
Waterbury Hospital (affiliated with Yale University), Waterbury, Connecticut

September, 1978 – June, 1982
Doctor of Medicine Degree
Albert Einstein College of Medicine, Medical Division, Bronx, New York

June, 1974
Master of Arts in Science Education
Cornell University, Graduate Division, Department of Chemistry and School of Education, Ithaca, New York

June, 1968
Bachelor of Arts in Mathematics and
Bachelor of Science in Chemistry with Highest Distinction
University of Kansas, Lawrence, Kansas

RESEARCH AND ACADEMIC POSITIONS:

Lecturer in Chemistry, Cornell University
Full-time faculty 1974-1978

Developed and implemented academic support services for minority students. Taught departmental courses in general and organic chemistry. Responsible for academic support services for all students in general chemistry.

Program Instructor, Cornell University
COSEP (Minority), Summers 1972-1973

Taught pre-freshman chemistry course to incoming freshman science majors.

Research Associate, International Population Program and Cornell University Science, Technology and Society Program, Caracas, Venezuela, Summer, 1971

Designed flow model of municipal family planning services with aim of improving efficiency and utilization of clinical services.

HONORS: University of Kansas, Wade Scholarship in Mathematics, Donnelly Scholarship, Departmental Highest Distinction in Chemistry.

Cornell University, DuPont Outstanding Teacher Award

PUBLICATIONS: Anderson, D.C. and Paden, P.Y.: Passive Avoidance Response Learning as a Function of Prior Tumbling Trauma. Pshychonomic Science, Volume IV, 1966.

Kovach, J.K., Paden, P.Y., and Wilson, G.: Stimulus Variables in the Elicitation and Short-Range Reversibility of Early Approach Philip York Paden, M.D.
Curriculum Vitae – Page 3
and Following Responses.

Journal of Comparative and Physiological Psychology, Volume 66 (1):175-178, 1968.

Paden, P.Y.: Instructor's Manual with Solutions to Accompany Sienko – Plane Chemical Principles and Properties. McGraw-Hill, New York, 1974.

DeLuise, V.P., Stern, J.T., and Paden, P.Y.: Uveitic Glaucoma Caused by Disseminated Meningococcemia. American Journal of Ophthalmology, 95:707, 1983.

Beyer, R.A., Paden, P.Y., Sobel, D.F., and Flynn, F.G.: Moyamoya Pattern of Vascular Occlusion After Radiotherapy for Glioma of the Optic Chiasm. Neurology, September, 1986.

CONSULTANT TO: Alcon Corporation (Fort Worth, Texas)
Heidelberg Engineering (Dossenheim, Germany)
Bio-Logic Aqua Technologies (Grants Pass, Oregon)

PROFESSIONAL ORGANIZATIONS: American Society of Cataract and Refractive Surgery
American Academy of Ophthalmology
Jackson County Medical Society

Certified by the American Board of Ophthalmology with Honors

CURRENT POSITION: Joined the Medical Eye Center in Medford, Oregon in 1986. Started Paden Eye Care Center (in Medford) in August, 2002. Specializing in diabetic eye care, improving visual and refractive results in cataract surgery, and computer imaging technology in glaucoma and diabetic retinopathy.

1-21-2004

Philip Paden

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EXHIBIT 2

THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE

Second Edition

Unabridged

Invention: METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE
Inventor: Sharon F. Kleyne
Application No. 09/614,790
Appeal Brief Filed April 7, 2006

Exhibit 3

: is equivalent to that of the High Mass but that is laborate in its celebration. Also called **sung Mass.** -05; < LL: lit., sung mass; see MASS, CANTATA]

al (mis′əl), *n.* **1.** *(sometimes cap.) Rom. Cath. Ch.* ook containing the prayers and rites used by the in celebrating Mass over the course of the entire **2.** any book of prayers or devotions. [1300–50; : ML *missāle*, n. use of neut. of *missālis*, equiv. to *i)* MASS + *-ālis* -AL¹]

:al stand′, a lectern for a missal, esp. one on an Also called **altar stand.**

ay (mis sā′), *v.*, **-said, -say·ing.** —*v.t.* **1.** to say :ak ill of; vilify; slander. **2.** to say wrongly. —*v.i.* speak wrongly or incorrectly. [1175–1225; ME *mis-* See MIS-¹, SAY¹] **—mis·say′er,** *n.*

eem (mis sēm′), *v.t. Archaic.* misbecome. -50; ME *missemen*. See MIS-¹, SEEM]

el thrush′ (mis′əl). See **mistle thrush.** [1765–

end (mis send′), *v.t.*, **-sent, -send·ing.** to send or rd, esp. mail, to a wrong place or person. [1400–50; 1E *missenden*. See MIS-¹, SEND]

hape (mis shāp′, mish-), *v.t.*, **-shaped, -shaped** ıap·en, **-shap·ing.** to shape badly or wrongly; de- [1400–50; late ME; see MIS-¹, SHAPE]

hap·en (mis shā′pən, mish-), *adj.* badly shaped; ned. [1350–1400; ME: ptp. of MISSHAPE; see -EN³] **·shap′en·ly,** *adv.* **—mis·shap′en·ness,** *n.*

ile (mis′əl *or, esp. Brit.*, -il), *n.* **1.** an object or :n for throwing, hurling, or shooting, as a stone, or arrow. **2.** See **guided missile. 3.** See **ballis- issile.** —*adj.* **4.** capable of being thrown, hurled, t, as from the hand or a gun. **5.** used or designed charging missiles. [1600–10; < L, neut. of *missilis*, to *miss(us)* (ptp. of *mittere* to send, throw) + *-ilis*

·leer (mis′ə lēr′), *n.* missileman. [MISSILE +

ile gap′, a lag in one country's missile produc- elative to the production of another country. 60]

le·man (mis′əl mən *or, esp. Brit.*, -il-), *n., pl.* **1.** a person who builds, designs, launches, or op- guided missiles. **2.** a technician or scientist whose ertains to missilery. Also called **missileer.** [1950– SSILE + -MAN]

le·ry (mis′əl rē), *n.* the science of the construc- ıd use of guided missiles. Also, **mis′sil·ry.** [1875– SILE + -RY]

ng (mis′ing), *adj.* lacking, absent, or not found: *ing person.* [1520–30; MISS¹ + -ING²]

ng link′, **1.** a hypothetical form of animal as- to have constituted a connecting link between the poid apes and humans, identified by some au- es as constituting the genus *Australopithecus.* **2.** ıing lacking for the completion of a series or se- . [1850–55]

·ol·o·gy (mis′ē ol′ə jē), *n. Christianity.* the the- ıl study of the mission of the church, esp. the char- ınd purpose of missionary work. [1920–25; MIS- + -O- + -LOGY]

on (mish′ən), *n.* **1.** a group or committee of per- ent to a foreign country to conduct negotiations, sh relations, provide scientific and technical assis- or the like. **2.** the business with which such a is charged. **3.** a permanent diplomatic establish- broad; embassy; legation. **4.** *Mil.* an operational sually assigned by a higher headquarters: *a mis- bomb the bridge.* **5.** *Aerospace.* an operation de- to carry out the goals of a specific program: *a nission.* **6.** a group of persons sent by a church to on religious work, esp. evangelization in foreign ınd often to establish schools, hospitals, etc. **7.** an shment of missionaries in a foreign land; a mis- church or station. **8.** a similar establishment in gion. **9.** the district assigned to a missionary. **10.** ıary duty or work. **11.** an organization for carry- missionary work. **12.** Also called **rescue mis-** shelter operated by a church or other organiza- fering food, lodging, and other assistance to needy s. **13. missions,** organized missionary work or es in any country or region. **14.** a church or a dependent on a larger church or denomination. series of special religious services for increasing ıs devotion and converting unbelievers: *to preach on.* **16.** an assigned or self-imposed duty or task; vocation. **17.** a sending or being sent for some r purpose. **18.** those sent. —*adj.* **19.** of or per- to a mission. **20.** *(usually cap.)* noting or per- to a style of American furniture of the early 20th , created in supposed imitation of the furnishings Spanish missions of California and characterized use of dark, stained wood, by heaviness, and by e plainness. Also called **foreign mission** (for defs. 1590–1600; 1925–30 for def. 4; < L *missiōn-* (s. of a sending off, equiv. to *miss(us)* (ptp. of *mittere* .) + *-iōn-* -ION] **—mis′sion·al,** *adj.*

on (mish′ən), *n.* a city in S Texas. 22,589.

on·ar·y (mish′ə ner′ē), *n., pl.* **-ar·ies,** *adj.* —*n.* Also, **mis′sion·er. 1.** a person sent by a church into an area to carry on evangelism or other activities, as educational or hospital work. **2.** a person strongly in favor of a program, set of principles, etc., who attempts to persuade or convert others. **3.** a person who is sent on a mission. —*adj.* **4.** pertaining to or connected with religious missions. **5.** engaged in such a mission, or devoted to work connected with missions. **6.** reflecting or prompted by the desire to persuade or convert others: *the missionary efforts of political fanatics.* **7.** characteristic of a missionary. [1635–45; < NL *missiōnārius*. See MISSION, -ARY]

mis′sionary apostol′ic, *pl.* **missionaries apostolic.** *Rom. Cath. Ch.* an honorary title conferred by the pope on certain missionaries.

mis′sionary posi′tion, a position for sexual intercourse in which the couple lies face to face with the male on top. [1965–70; so called because it was allegedly favored by Christian missionaries working among indigenous peoples, in preference to positions in which the man approaches the woman from behind]

Mis′sionary Ridge′, a ridge in NW Georgia and SE Tennessee: Civil War battle 1863.

mis′sion control′, *Aerospace.* a command center for the control, monitoring, and support of activities connected with manned space flight. Also called **mis′sion control′ cen′ter.** [1960–65]

mis·sion·ize (mish′ə niz′), *v.*, **-ized, -iz·ing.** —*v.i.* **1.** to conduct missionary work. —*v.t.* **2.** to conduct missionary work in or among. Also, *esp. Brit.*, **mis′sion·ise′.** [1820–30; MISSION + -IZE]

mis′sion spe′cialist, *U.S. Aerospace.* the crew member of a space shuttle who is assigned primary responsibility for carrying out operations related to the payload of the shuttle. [1975–80]

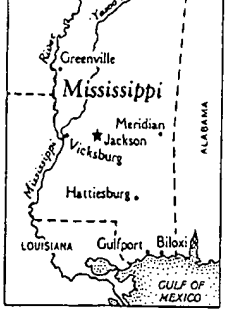
Mis′sion Vi·e′jo (vē ā′hō), a city in SW California. 50,666.

mis·sis (mis′iz, -is), *n.* **1.** *Older Use.* wife: *I'll have to ask the missis.* **2.** the mistress of a household. Also, **missus.** [1780–90; var. of MISTRESS]

miss·ish (mis′ish), *adj.* prim; affected; prudish. [1785–95; MISS² + -ISH¹] **—miss′ish·ness,** *n.*

Mis·sis·sau·ga (mis′ə sô′gə), *n.* a city in SE Ontario, in S Canada, on the SW shore of Lake Ontario; suburb of Toronto. 315,056.

Mis·sis·sip·pi (mis′ə sip′ē), *n.* **1.** a state in the S United States. 2,520,638; 47,716 sq. mi. (123,585 sq. km). *Cap.:* Jackson. *Abbr.:* MS (for use with zip code), Miss. **2.** a river flowing S from N Minnesota to the Gulf of Mexico: the principal river of the U.S. 2470 mi. (3975 km) long; from the headwaters of the Missouri to the Gulf of Mexico 3988 mi. (6418 km) long.



Mis·sis·sip·pi·an (mis′ə sip′ē ən), *adj.* **1.** of or pertaining to the state of Mississippi or the Mississippi River. **2.** *Geol.* noting or pertaining to a period of the Paleozoic Era, occurring from about 345 million to 310 million years ago and characterized as the age of amphibians. See table under **geologic time.** —*n.* **3.** a native or inhabitant of Mississippi. **4.** *Geol.* the Mississippian Period or System: the former is sometimes considered an epoch of the Carboniferous Period. [1765–75, *Amer.*; MISSISSIPPI + -AN]

mis·sive (mis′iv), *n.* **1.** a written message; letter. —*adj.* **2.** sent or about to be sent, esp. of a letter from an official source. [1400–50; late ME *(letter) missive* < ML *(littera) missiva* sent (letter), equiv. to L *miss(us)* (ptp. of *mittere* to send) + *-iva*, fem. of *-ivus* -IVE]

Miss′ Ju′lie, a play (1888) by Strindberg.

Mis·so·lon·ghi (mis′ə lông′gē), *n.* a town in W Greece, on the Gulf of Patras: Byron died here 1824. 11,614. Also, **Mesolonghi.**

Mis·sou·la (mi zōō′lə), *n.* a city in W Montana. 33,388.

Mis·sour·i (mi zŏŏr′ē, -zōōr′ə), *n., pl.* **-sour·is,** *(esp. collectively)* **-sour·i** for 3. **1.** a state in the central United States. 4,917,444; 69,674 sq. mi. (180,455 sq. km). *Cap.:* Jefferson City. *Abbr.:* MO (for use with zip code), Mo. **2.** a river flowing from SW Montana into the Mississippi N of St. Louis, Mo. 2723 mi. (4382 km) long. **3.** a member of a North American Indian tribe belonging to the Siouan linguistic stock, located on the Missouri River in early historic times and now extinct as a tribe. **4. from Missouri,** *Informal.* unwilling to accept something without proof; skeptical: *I'm from Missouri—you'll have to show me that you're right.* **—Mis·sour′i·an,** *adj., n.*



Missour′i Cit′y, a city in SE Texas. 24,533.

Missour′i Com′promise, *U.S. Hist.* an act of Congress (1820) by which Missouri was admitted as a slave state, Maine as a free state, and slavery was prohibited in the Louisiana Purchase north of latitude 36°30′N, except for Missouri. Cf. **Kansas-Nebraska Act.**

Missour′i gourd′, calabazilla.

Missour′i meer′schaum, corncob (def. 2).

miss·out (mis′out′), *n.* (in the game of craps) a losing throw of the dice. [1925–30; n. use of v. phrase *miss out*]

mis·speak (mis spēk′), *v.t., v.i.*, **-spoke, -spok·en, -speak·ing. 1.** to speak, utter, or pronounce incorrectly. **2.** to speak inaccurately, inappropriately, or too hastily. [1150–1200; ME *misspeken*; see MIS-¹, SPEAK; cf. OE *misprecan* to murmur]

mis·spell (mis spel′), *v.t., v.i.*, **-spelled** or **-spelt, -spell·ing.** to spell incorrectly. [1645–55; MIS-¹ + SPELL¹]

mis·spell·ing (mis spel′ing), *n.* **1.** the act of spelling incorrectly: *Note his misspelling of that word.* **2.** an incorrectly spelled word: *You have three misspellings in your letter.* [1685–95; MIS-¹ + SPELLING]

mis·spend (mis spend′), *v.t.*, **-spent, -spend·ing.** to spend wrongly or unwisely; squander; waste. [1350–1400; ME. See MIS-¹, SPEND] **—mis·spend′er,** *n.*

mis·spent (mis spent′), **1.** pt. and pp. of **misspend.** —*adj.* **2.** spent wrongly or unwisely; wasted: *misspent youth.*

mis·state (mis stāt′), *v.t.*, **-stat·ed, -stat·ing.** to state wrongly or misleadingly; make a wrong statement about. [1640–50; MIS-¹ + STATE] **—mis·state′ment,** *n.* **—mis·stat′er,** *n.*

—Syn. misreport, falsify, alter, distort.

mis·step (mis step′), *n.* **1.** a wrong step. **2.** an error or slip in conduct; faux pas. [1250–1300; ME *missteppen*. See MIS-¹, STEP]

—Syn. 2. fault, transgression, lapse, indiscretion.

mis·strike (mis strīk′), *n. Numis.* a coin having the design stamped off center. [1955–60; MIS-¹ + STRIKE]

mis·sus (mis′əz, -əs), *n.* missis.

miss·y (mis′ē), *n., pl.* **miss·ies.** *Informal.* young miss; girl. [1670–80; MISS² + -Y²]

mist (mist), *n.* **1.** a cloudlike aggregation of minute globules of water suspended in the atmosphere at or near the earth's surface, reducing visibility to a lesser degree than fog. **2.** a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief.* **3.** something that dims, obscures, or blurs: *the mist of ignorance.* **4.** a haze before the eyes that dims the vision: *a mist of tears.* **5.** a suspension of a liquid in a gas. **6.** a drink of liquor served over cracked ice. **7.** a fine spray produced by a vaporizer to add moisture to the air for breathing. —*v.i.* **8.** to become misty. **9.** to rain in very fine drops; drizzle (usually used impersonally with *it* as subject): *It was misting when they went out for lunch.* —*v.t.* **10.** to make misty. **11.** to spray (plants) with a finely diffused jet of water, as a means of replacing lost moisture. [bef. 900; (n.) ME, OE; c. D, LG, Sw *mist*; akin to Gk *omichlē* fog, Russ *mgla* mist, Skt *megha* cloud; (v.) ME *misten*, OE *mistian*, deriv. of the n.] **—mist′less,** *adj.*

—Syn. 3, 4. See **cloud.**

mist., (in prescriptions) a mixture. [< L *mistūra*]

mis·tak·a·ble (mi stā′kə bəl), *adj.* capable of being or liable to be mistaken or misunderstood. [1640–50; MIS-

CONCISE PRONUNCIATION KEY: *act, cāpe, dâre, pärt; set, ēqual; if, ice; ox, ôver, ôrder, oil, bo͝ok, bo͞ot, out; up, ûrge; child; sing; shoe; thin, that; zh as in treasure.* ə = *a as in alone, e as in system, i as in easily, o as in gallop, u as in circus;* ˈ as in *fire* (fīˈər), *hour* (ouˈər). l and n can serve as syllabic consonants, as in *cradle* (krādˈl), and *button* (butˈn). See the full key inside the front cover.

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SECOND COLLEGE EDITION



WEBSTER'S NEW WORLD DICTIONARY

OF THE AMERICAN LANGUAGE

DAVID B. GURALNIK, *Editor in Chief*

SIMON AND SC

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Invention: METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE
Inventor: Sharon F. Kleyne
Application No. 09/614,790
Appeal Brief Filed April 7, 2006

Exhibit 4

disorderly conduct *Law* any petty offense against public peace, safety, or order
disorderly house any establishment where offenses against public peace, safety, or order habitually occur; esp., a house of prostitution
dis·or·gan·ize (dis ôr′gə nīz′) *vt.* **-ized′, -iz′ing** [Fr. *désorganiser:* see DIS- & ORGANIZE] to break up the order, arrangement, or system of; throw into confusion or disorder —**dis·or′gan·i·za′tion** *n.*
dis·o·ri·ent (-ôr′ē ent′) *vt.* [Fr. *désorienter:* see DIS- & ORIENT, *v.*] 1. orig., to turn away from the east 2. to cause to lose one's bearings 3. to confuse mentally, esp. with respect to time, place, and the identity of persons and objects Also **dis·o′ri·en·tate′** (-ən tāt′) **-tat′ed, -tat′ing** —**dis·o′ri·en·ta′tion** *n.*
dis·own (-ōn′) *vt.* to refuse to acknowledge as one's own; repudiate; cast off
dis·par·age (-par′ij) *vt.* **-aged, -ag·ing** [ME. *disparagen* < OFr. *desparagier*, to marry one of inferior rank < *des-* (see DIS-) + *parage*, rank < *per*, PEER¹] 1. to lower in esteem; discredit 2. to speak slightingly of; show disrespect for; belittle —**dis·par′ag·ing** *adj.* —**dis·par′ag·ing·ly** *adv.*
SYN. —**to disparage** is to attempt to lower in esteem, as by insinuation, invidious comparison, faint praise, etc.; to **depreciate** is to lessen (something) in value as by implying that it has less worth than is usually attributed to it *[he depreciated* her generosity*]*; **decry** implies vigorous public denunciation, often from the best of motives *[to decry* corruption in government*]*; **belittle** is equivalent to **depreciate**, but stresses a contemptuous attitude in the subject; **minimize** suggests an ascription of the least possible value or importance *[don't minimize* your own efforts*]* —*ANT.* **extol, praise, magnify**
dis·par·age·ment (-mənt) *n.* 1. a disparaging or being disparaged; detraction 2. anything that discredits
dis·pa·rate (dis′pər it) *adj.* [L. *disparatus*, pp. of *disparare*, to separate < *dis-*, apart, not + *parare*, to make equal < *par*, equal: see PAR] essentially not alike; distinct or different in kind; unequal —*SYN.* see DIFFERENT —**dis′pa·rate·ly** *adv.* —**dis′pa·rate·ness** *n.*
dis·par·i·ty (dis par′ə tē) *n., pl.* **-ties** [Fr. *disparité* < ML. *disparitas* < L. *dispar*, unequal: see DIS- & PAR] 1. inequality or difference, as in rank, amount, quality, etc. 2. unlikeness; incongruity
dis·part (-pärt′) *vt., vi.* [prob. < It. *dispartire* < L., to divide < *dis-*, apart, from + *partire*, to part, divide < *pars* (gen. *partis*), a part] [Archaic] to divide into parts; separate
dis·pas·sion·ate (-pash′ən it) *adj.* free from passion, emotion, or bias; calm; impartial —*SYN.* see FAIR¹ —**dis·pas′sion** *n.* —**dis·pas′sion·ate·ly** *adv.*
dis·patch (-pach′) *vt.* [Sp. *despachar* & It. *dispacciare*, to send off, lit., to remove impediments, hence facilitate < OFr. *despeechier* < *des-* (see DIS-) + (*em*)*peechier*, to impede < LL. *impedicare*, to entangle < L. *in-*, in + *pedica*, a shackle < *pes*, FOOT] 1. to send off or out promptly, usually on a specific errand or official business 2. to put an end to; kill 3. to finish quickly or promptly 4. [Colloq.] to eat up quickly —*n.* 1. a dispatching; sending out or off 2. an act of killing 3. efficient speed; promptness 4. a message, esp. an official message 5. a news story sent to a newspaper, radio station, etc., as by a special reporter or news agency —*SYN.* see HASTE, KILL¹
dis·patch·er (-ər) *n.* 1. a person who dispatches ☆2. a transportation worker who sends out trains, buses, trucks, etc. according to a schedule
dis·pel (dis pel′) *vt.* **-pelled′, -pel′ling** [ME. *dispellen* < L. *dispellere* < *dis-*, apart + *pellere*, to drive < IE. base **pel-*, whence FELT¹] to scatter and drive away; cause to vanish; disperse —*SYN.* see SCATTER
dis·pen·sa·ble (dis pen′sə b'l) *adj.* [ML.(Ec.) *dispensabilis*] 1. that can be dispensed, dealt out, or administered 2. that can be dispensed with; not important 3. *R.C.Ch.* that can be permitted by dispensation —**dis·pen′sa·bil′i·ty** *n.*
dis·pen·sa·ry (-sə rē) *n., pl.* **-ries** [< ML. *dispensarius*, one who dispenses, steward] a room or place, as in a school, camp, or factory, where medicines and first-aid treatment are available
dis·pen·sa·tion (dis′pən sā′shən, -pen-) *n.* [ME. *dispensacioun* < OFr. *despensation* < L. *dispensatio*, management, charge < pp. of *dispensare*] 1. a dispensing, or giving out; distribution 2. anything dispensed or distributed 3. the system by which anything is administered; management 4. any release or exemption from an obligation 5. *Law* the suspension of a statute in a specific case for extenuating reasons 6. *R.C.Ch.* an exemption or release from the provisions of a specific church law 7. *Theol. a)* the ordering of events under divine authority *b)* any religious system —**dis′pen·sa′tion·al** *adj.*
dis·pen·sa·tor (dis′pen sāt′ər) *n.* [ME. *dispensatour* < L. *dispensator*, manager < pp. of *dispensare*] [Obs.] one who dispenses; distributor or administrator
dis·pen·sa·to·ry (dis pen′sə tôr′ē) *n., pl.* **-ries** [ML. *dispensatorium* < LL. *dispensatorius*, of management or control < L. *dispensare:* see ff.] 1. a handbook on the preparation and use of medicines; pharmacopoeia 2. [Obs.] a dispensary
dis·pense (-pens′) *vt.* **-pensed′, -pens′ing** [ME. *dispensen* < OFr. *despenser* < L. *dispensare*, to pay out < pp. of *dispendere*, to weigh out < *dis-*, out + *pendere*, to weigh: see PEND] 1. to give or deal out; distribute 2. to prepare and give out (medicines, prescriptions, etc.) 3. to administer *[to dispense* the law justly*]* 4. to exempt; excuse —*SYN.* see DISTRIBUTE —**dispense with** 1. to get rid of; do away with 2. to do without; manage without
dis·pen·ser (-pen′sər) *n.* a person or thing that dispenses; specif., a container designed to dispense its contents in handy units or portions
dis·peo·ple (-pē′p'l) *vt.* **-pled, -pling** *same as* DEPOPULATE
di·sper·mous (di spur′məs) *adj.* [DI-¹ + SPERMOUS] *Bot.* having two seeds
dis·per·sal (dis pur′s'l) *n.* a dispersing or being dispersed; distribution
dis·perse (-purs′) *vt.* **-persed′, -pers′ing** [ME. *dispersen* < L. *dispersus*, pp. of *dispergere*, to scatter abroad < *dis-*, out + *spargere*, to scatter, strew: for IE. base see SPROUT] 1. to break up and scatter in all directions; spread about; distribute widely 2. to dispel (mist, etc.) 3. to break up (light) into its component colored rays —*vi.* to break up and move in different directions; scatter —*SYN.* see SCATTER —**dis·pers′er** *n.* —**dis·pers′i·ble** *adj.*
disperse system a two-phase colloidal system consisting of the colloidal particles (**disperse phase**) and the medium in which they are suspended (**disperse medium**)
dis·per·sion (dis pur′zhən, -shən) *n.* [ME. *dispersioun* < OFr. *dispersion* < L. *dispersio*] 1. a dispersing or being dispersed 2. the breaking up of light into component colored rays, as by means of a prism 3. the resolution of a complex electromagnetic radiation into components in accordance with some characteristic, as wavelength 4. the variation or scattering of data around a median value 5. a colloidal system with its dispersed particles and the medium in which these are suspended 6. [D-] *same as* DIASPORA
dis·per·sive (-siv) *adj.* dispersing or tending to disperse —**dis·per′sive·ly** *adv.*
dis·per·soid (-soid) *n.* a colloidal system, as an emulsion, in which the colloidal particles are quite small and well suspended in the disperse medium
dis·pir·it (di spir′it) *vt.* to lower the spirits of; make sad, discouraged, or apathetic; depress; deject —**dis·pir′it·ed** *adj.* —**dis·pir′it·ed·ly** *adv.*
dis·pit·e·ous (dis pit′ē əs) *adj.* [var. of DESPITEOUS] [Archaic] without pity or mercy; ruthless
dis·place (-plās′) *vt.* **-placed′, -plac′ing** [OFr. *desplacer:* see DIS- & PLACE] 1. to move from its usual or proper place 2. to remove from office; discharge 3. to take the place of; replace *[a* ship *displaces* a certain amount of water*]* —*SYN.* see REPLACE
displaced person a person forced from his country, esp. as a result of war, and left homeless elsewhere
dis·place·ment (-mənt) *n.* 1. a displacing or being displaced 2. *a)* the weight or volume of a fluid displaced by a floating object; specif., the weight of water, in long tons, displaced by a ship *b)* the volume displaced by a stroke of a piston 3. the difference between a later position of a thing and its original position 4. *Geol.* a fault 5. *Psychiatry* a defense mechanism in which an emotion is transferred to another, more acceptable object
dis·plant (dis plant′, -plänt′) *vt.* [Obs.] to transplant, dislodge, or displace
dis·play (-plā′) *vt.* [ME. *displeien* < OFr. *despleier* < L. *displicare*, to scatter, unfold < *dis-*, apart + *plicare*, to fold: for IE. base see FLAX] 1. to unfold; spread out; unfurl 2. to unfold to the eye; put or spread out so as to be seen; exhibit 3. to unfold to the mind; disclose; reveal 4. to print conspicuously, as in large or fancy type —*n.* 1. a displaying; exhibition 2. anything displayed; exhibit 3. showy exhibition; ostentation 4. *a)* a manifestation *[a display* of courage*] b)* a mere show of something that is not genuine *[a display* of sympathy*]* —*adj.* designating printing type in larger sizes, used for headings, advertisement, etc. —*SYN.* see SHOW
dis·please (-plēz′) *vt., vi.* **-pleased′, -pleas′ing** [ME. *displesen* < OFr. *desplaisir* < VL. **displacere*, for L. *displicere* < *dis-*, not + *placere:* see PLEASE] to fail to please or to be disagreeable (to); annoy; offend; irritate
dis·pleas·ure (-plezh′ər) *n.* [ME. *displesir* < OFr. *desplaisir*, inf. used as n.: see prec.] 1. the fact or feeling of being displeased; dissatisfaction, disapproval, annoyance, etc. 2. [Archaic] discomfort, sorrow, trouble, etc. —*SYN.* see OFFENSE
dis·plode (-plōd′) *vt., vi.* **-plod′ed, -plod′ing** [L. *displodere* < *dis-*, apart + *plaudere*, to applaud] [Obs.] *same as* EXPLODE —**dis·plo′sion** (-plō′zhən) *n.*
dis·plume (-plōōm′) *vt.* **-plumed′, -plum′ing** [Ra... *same as* DEPLUME
dis·port (-pôrt′) *vi.* [ME. *disporten*, to bear, support < OFr. *desporter* < *des-* (see DIS-) + *porter* < L. *portare*, carry: see PORT³] to indulge in amusement; play; fro... —*vt.* to amuse or divert (oneself) —*n.* [Archaic] a... porting; amusement; play
dis·pos·a·ble (-pō′zə b'l) *adj.* 1. that can be thrown a... after use *[disposable* bottles*]* 2. that can be disposed... restricted to any specific use
dis·pos·al (-pō′z'l) *n.* 1. the act of disposing; spe... *a)* arrangement in a particular order *[the disposal* of furniture in a room*] b)* a dealing with matters or setti... of affairs *c)* a giving away; transfer; bestowal *d)* a ge... rid of 2. the power to dispose of 3. *same as* DISP...

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PATENT & TRADEMARK OFFICE

Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Sharon F. Kleyne	:	Group Art Unit: 1619
Serial No. 09/614,790	:	Examiner: Michael Willis
Filed: July 12, 2000	:	Tel. No. (703) 305-1679
For a Patent for METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	

DECLARATION OF DR. WILLIAM D. MATHERS
37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

1. I, William D. Mathers, MD, am a Professor of Ophthalmology at Oregon Health and Science University – Casey Eye Institute in Portland Oregon. A copy of my curriculum vitae is attached hereto and forms a part of this declaration. I am a paid consultant to Rogue Valley Natural Springs, Inc., a company that commercializes an eye-moisturizing product described and claimed in the application. This company was founded by Sharon F. Kleyne, the inventor of the present application. I am also a shareholder in the company. I am familiar with the prosecution of this application in the U.S. Patent Office.

2. I am submitting this Declaration to provide data that shows that Nature's Tears®, the commercial embodiment of the invention claimed in this application, is more effective and is more convenient to use than are other products that are available for the symptomatic relief of dry eye. Nature's Tears delivers a very small quantity of aqueous fluid to the eye in the form of

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a mist. The fluid that is delivered to the eye by the use of Nature's Tears is sufficient to moisturize the surface of the eye and does not disrupt the tri-laminar tear film that is present on the surface of the eye. I was one of three consultants who completed a study to evaluate patient response to Nature's Tears in comparison to other products that patients had previously used for symptomatic relief of eye discomfort.

3. Thirty nine (39) patients were surveyed. Of the 39 patients, 33 (84%) had dry eye. The remaining 6 (16%) were given Nature's Tears for various reasons, such as ocular surface allergies or irritation. Of the 39 patients, 35 (89%) had previously used other eye care products and of these 72% (25) had experienced favorable results with those products. The patients were given Nature's Tears to use freely for 2 weeks, as needed. Telephone interviews were conducted after the two week period.

4. In the survey, the patients were asked if Nature's Tears was more effective, less effective, or about the same compared to other products. The patients were asked if Nature's Tears was more convenient, less convenient, or about the same compared to other products. The patients were asked if they would or would not purchase Nature's Tears.

5. Of the 39 patients surveyed, 72% (28) found Nature's Tears to be more effective than the other products they had used. 24% (9) said that Nature's Tears was about the same as other products they had used. One (3%) said that it was less effective.

6. Of the 39 patients surveyed, 83% (32) said that Nature's Tears was more convenient to use compared to other products. Two of the patients found it less convenient and two of the patients said it was about the same.

7. Of the 39 patients surveyed, 83% said they would purchase Nature's Tears. 17% said that they would not.

8. The data from this study establishes that Nature's Tears eye mist is more effective and more convenient to use than other available products for topical application to the surface of the eye to treat ocular discomfort, such as due to dry eye. The data also shows that most patients who try Nature's Tears would purchase Nature's Tears.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Jan 25th 2004
Date

William D. Mathers, MD

OREGON HEALTH SCIENCES UNIVERSITY
CASEY EYE INSTITUTE
CURRICULUM VITAE

WILLIAM D. MATHERS, M.D.

I. Personal Data

Citizenship Status: U.S.
Birth date: 12/01/47

II. Education

1969	B.S.	Chemistry, Allegheny College, Meadville, PA
1973	M.D.	Stanford Medical School, Stanford, CA

III. Post-Graduate Education

1973-74	Intern	Surgery, Stanford Medical School, Stanford, CA
1975-77	Resident	Anesthesiology, Stanford Medical School, Stanford, CA
1982-85	Resident	Ophthalmology, University of Washington School of Medicine, Seattle, WA
1985-86	Fellow	Cornea and External Disease, Georgetown University Medical School, Washington, D.C.

IV. Academic Appointments

1977-79	Assistant Professor of Anesthesiology, Stanford Medical School, Stanford, CA
1985-86	Clinical Instructor, Department of Ophthalmology, Georgetown University, Washington, D.C.
1985-86	Faculty Instructor, Center for Sight, Georgetown University Medical Center, Washington, D.C.
1986-88	Assistant Professor of Ophthalmology, University of Arizona, Tucson, AZ.
1988-92	Assistant Professor of Ophthalmology, and Director, Cornea Service, Georgetown University, Washington, D.C.
1992-94	Associate Professor (without tenure), and Director, Cornea Service, Department of Ophthalmology, University of Iowa
1994-97	Associate Professor, (with tenure), Department of Ophthalmology, College of Medicine, University of Iowa, Iowa City, IA
1997-99	Professor, Department of Ophthalmology, College of Medicine, University of Iowa, Iowa City, IA.
1999-	Professor of Ophthalmology, Casey Eye Institute, Oregon Health Sciences University, Portland, Oregon

V. Other Positions Pertaining to Current Professional Appointments

1977-79	Chief of Cardiac Anesthesia, Veterans Administration Hospital, Palo Alto, CA
1979-80	Private Practice in Anesthesiology, Albuquerque, NM
1980-82	Private Practice in Anesthesiology, Fresno, CA

VI. Certification and Licensure

A. Certification:

1. American Board of Anesthesiology 1980 No. 9558
2. American Board of Ophthalmology 1987

B. Licensure:

1. California	1974	Perm.	G27004	12/31/93	(not renewed)
2. New Mexico	1979	Perm.	79-225	1/1/83	(not renewed)
3. Washington	1982	Perm.	0019810	3/31/86	(not renewed)
4. Washington, DC	1985	Perm.	15023	12/31/92	(not renewed)
5. Arizona	1986	Perm.	16193	1/1/88	(not renewed)
6. Iowa	1992	Perm.	28643	12/1/99	(not renewed)
7. Oregon	1999	Perm	MD21605	12/31/01	

VII. Professional Affiliations (including offices held)

- Oregon Association of Ophthalmology
- American Academy of Ophthalmology
- American Medical Association
- Washington State Academy of Ophthalmology
- Castroviejo Society
- Association for Research in Vision and Ophthalmology
- International Society for Contact Lens Research
- Contact Lens Association of Ophthalmologists (President 97-98)
- Eye Bank Association of America
- Society for Cataract and Refractive Surgery
- American Board of Ophthalmology - Associate
- Research to Prevent Blindness
- American Diabetes Association
- Pan American Association for Contact Lenses and Refraction (President 97-98)
- American Association for the Advancement of Science
- American Society of Cataract and Refractive Surgery
- Society of Protozoologists
- International Society of Refractive Surgery
- FDA Ophthalmic Devices Panel member
- Society for Neuroscience member
- Founder/Director, Chair Scientific review committee- Wadsworth Foundation for Multiple Sclerosis Research

VIII. Areas of Research Interest

1. Gene regulation in the lacrimal glandDry eye and tear measurement
2. Uveitis -leukocyte visualization in-vivo
3. Meibomian gland disease
4. In vivo confocal microscopy of keratitis
5. Genetic basis of corneal disease
6. Acanthamoeba keratitis diagnosis and treatment

IX. Current Projects

1. Stimulation stress in the Lacrimal Gland -Gene Array studies
2. Confocal examination of Scleritis and conjunctivitis
3. Keratitis risk assessment
4. Confocal microscopy of Acanthamoeba Keratitis and corneal dystrophy
5. 3D Confocal Microscopy of Corneal structures

X. Other Professional Activities

1991-2000	CLAO Board of Directors
1993	CLAO Journal editorial board
1993-1996	Cornea Journal editorial board
1994-2000	NEI-VISA Study Section, invited committee member
1993-1999	CLAO Board of Directors, Scientific Program Director
1995-2000	Castroviejo Society, board member
1997	CLAO President
1998-2000	Schepens Scientific Advisory Committee member
1999-2000	Pan American Association for Contact Lenses and Refraction, President
2001	Founding member, chair scientific review: Multiple Sclerosis Foundation
2001	FDA Ophthalmic Devices Committee Member
2001	Nugent Award for Corneal Research-recurring support
2002	RPB Physician-Scientist Award

XI. Collegiate, University, University Hospitals, and National Committees

National Committees:

1989	FDA Joint Council on Contact Lens Compliance
1990	Contact Lenses Council
1990	CLAO Industrial Standard Committee
1991	CLAO Continuing Medical Education Committee
1992	Scientific Program Director for CLAO & Annual Meeting
1992	Medical Director Iowa Lions Eye Bank
1993	Editorial Board CLAO Journal
1993	Associate Director Eye Injury Registry of Iowa
1994	Editorial Board of Cornea
1996	EBAA Eye Bank Assoc of Am. Paton committee
1994-2000	VIS-A Study Section, NIH
2001-2003	FDA Ophthalmic Devices Panel member

XII. Honors and Awards

- American Field Service Scholarship, 1963
- ALCOA National Scholarship, 1964
- American Academy of Ophthalmology Honor Award, 1993
- Tuohy Lectureship, Contact Lens Association of America Award, 1994
- American Ophthalmologic Society (nominated)
- Keynote Address-Second International Conference on the Lacrimal Gland 1996
- Kersley Memorial lecture, Moorefields England 1999
- Behren's Memorial lecture, CLAO Annual Meeting 2000
- RPB Physician Scientist Award
- Nugent Award for Corneal Research

XIII. Financial Resources (Grants and Contracts)

A. Federal (NEI)

Tear Production, the Ocular Surface, and Contact Lenses National Eye Institute (EY04361-05), funded 1986-1991 William D. Mathers, M.D., Co-Investigator	$955,000
Meibomian Gland Dysfunction in Chronic Blepharitis National Eye Institute (EY10151-01), submitted 2/1/1991 (3-year grant awarded 12/91; activate 9/92) William D. Mathers, M.D., Principal Investigator	$562,187
Tear Function in Blepharitis and Dry Eye National Eye Institute (R01EY10164-04) funded 12/01/1995 (5-year grant) William D. Mathers, M.D., Principal Investigator	$1,078,020
Molecular Genetics of Corneal Dystrophies National Institutes of Health (R01EY11543-01) awarded 6/96 (5 year grant) William D. Mathers, M.D., Co-Investigator	$800,000
Confocal Diagnosis of Acanthamoeba Keratitis National Institutes of Health (1RO1EY11667-01) Awarded 11/96 (2 year grant) William D. Mathers, M.D., Principal Investigator	$210,000
Tear Function in Blepharitis and Dry Eye National Eye Institute (7R01-EY10151-08) funded 3/99- 2/01 (grant forwarded to OHSU) William D. Mathers, M.D., Principal Investigator	$242,634.00
Enhanced Diagnosis of Acanthamoeba Keratitis National Institutes of Health (7RO1-EY11667-03) Awarded 3/99-9/00 (grant forwarded to OHSU) William D. Mathers, M.D., Principal Investigator	$71,493.00
Ocular Inflammation and Dry Eye Medical Research Foundation of Oregon Awarded 12/1999 William D. Mathers, M.D. Principle Investigator	$25,000.00
Nugent Award for Corneal Research Awarded 2001 yearly William D. Mathers, M.D.	$150,000.00
RPB Inc. Physician-Scientist Award Awarded 2001 William D. Mathers, M.D.	$55,000.00

In Vivo Imaging of Leukocyte-Endothelial Dynamics $144,941.00
DHHS NIH National Eye Institute
Awarded 2003 (RO3-EY014013-01)
William D. Mathers, MD

B. **College of Medicine**

Color Specular Microscopy of the Dry Eye $ 6,000
to Evaluate Currently Used Medications
Biomedical Research Support Grant Committee (BRSG),
funded 1987 - College of Medicine, University of Arizona

Ocular Inflammation and Dry Eye $25,000
Medical Research Foundation of Oregon
Awarded 12/1999
William D. Mathers, M.D. Principle Investigator

Acanthamoeba Eye Infections $25,000
Collins Medical Trust
Awarded 7/00
William D. Mathers, M.D. Principle Investigator

C. **Other** Financial Resources (other Grants and Contracts)

Phase I Tolerance Study of a 0.15% Concentration $ 29,009
E7A (AF2975) in Normal Volunteers and in
Volunteers with "Dry Eye"
Angelini Pharmaceuticals, Inc, funded 1975
William D. Mathers, M.D., Principal Investigator

Bromhexine Treatment for Sjögrens Syndrome $ 40,500
Boehringer Ingelheim, funded 1991
William D. Mathers, M.D., Principal Investigator

Meibomian Gland Dysfunction and Contact Lens $ 10,000
Intolerance
Bausch & Lomb, funded 1990
William D. Mathers, M.D., Principal Investigator

Propamidine Use in Acanthamoeba Keratitis $ 2,000
Bausch & Lomb funded 1989
William D. Mathers, M.D., Co-Investigator

Penetrating Keratoplasty Collagen $ 2,600
Synthesis Analysis
Lions Eye Bank of Arizona, funded 1987

Efficacy of Temporary Punctal Occlusion $ 2,000
Lacrimedics, funded 1987

Dose Response of Epidermal Growth Factor $ 4,000
on Corneal Stromal Wounds - AMGEN,
funded 1987

Specular Epithelial Changes With a New Preservative: Polyquad - Alcon, funded 1986 William D. Mathers, M.D., Principal Investigator	$ 4,000
Confocal Microscopy Grant Iowa Lions William D. Mathers, M.D., Principal Investigator	$ 40,000
Confocal Examination of Deposits After INTACTS Keravision Inc. funded 10/99 William D. Mathers, M.D., Principal Investigator	$ 2,887
Dry Eye & Sjogren's syndrome Daiichi Pharmaceutical Corp. funded William D. Mathers, M.D., Co-Investigator	

XIV. Bibliography

A. Papers Published or in Press

1. Samquist FH, **Mathers WD,** Brock-Utne J, Carr B, Canup C, Brown CR: A bioassay for a water-soluble Benzodiazepine against sodium thiopental. Anesthesiology 52:149-153, 1980.

2. **Mathers WD,** Grutzmacher RD: Lens implant calculations using an average of several formulas. CLAO Journal 12:216-218, 1986.

3. **Mathers WD,** Stevens G Jr., Rodrigues M, Chan CC, Gold J, Visvesvara GS, Lemp MA, Zimmerman LE: Immunopathology and electron microscopy of Acanthamoeba keratitis. American Journal of Ophthalmology 103:626-635, 1987.

4. **Mathers WD**: Occasional seizures that can follow retrobulbar anesthesia with bupivacaine 0.75%. Letter to the Editor. Annals of Ophthalmology 19:91, 1987.

5. **Mathers WD**: Cyanoacrylate adhesive application. Letter to the Editor. Ophthalmic Surgery 18:851, 1987.

6. **Mathers WD,** Lemp MA: Corneal rim cultures. Cornea 6:231-233, 1987.

7. **Mathers WD,** Kattan H, Earll J, Lemp M: Development of presenile cataracts in association with high serum levels of Phenytoin. Annals of Ophthalmology 19:291-292, 1987.

8. Fryczkowski AW, Sato SE, **Mathers WD,** Allinson RW, Sherman MD, Hodes BL: Architectonic structure of the blood vessels of the choroid. II. The submacular area. Klinika Oczna 90:5-8, 1988.

9. Fryczkowski AW, Sato SE, **Mathers WD,** Allinson RW, Sherman MD, Hodes BL: Angioarchitecture of the choroid. V. Peripheral choroid. The vortex veins. Klinika Oczna 90:81-86, 1988.

10. **Mathers WD,** Jester JV, Lemp MA: Return of human corneal sensitivity after penetrating keratoplasty. Archives of Ophthalmology 106:210-211, 1988.

11. **Mathers WD,** Sherman M, Fryczkowski A, Jester JV: Dose-dependent effects of epidermal growth factor on corneal wound healing. Investigative Ophthalmology & Visual Science 30:2403-2406, '89.

12. Lemp MA, **Mathers WD,** Gold JB: Surface cell morphology of the anesthetic human cornea: A color specular microscopic study. Acta Ophthalmologica Suppl (Copenh) 192:102-107, 1989.

13. Lemp MA, **Mathers WD**: Corneal epithelial cell movement in humans. Eye 3:438-445, 1989.

14. Mertz PH, Bouchard CS, **Mathers WD**, Goldman J, Shields WJ, Cavanagh HD: Corneal infiltrates associated with disposable extended wear soft contact lenses: A report of nine cases. CLAO Journal 16:269-272, 1990.

15. Horton JC, **Mathers WD**, Zimmerman LE: Pyogenic granuloma of the palpebral conjunctiva associated with contact lens wear. Cornea 9:359-361, 1990.

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- Lemp MA, **Mathers WD**, Jester JV, Cavanagh HD: "Color specular microscopy of the corneal epithelium in humans." 8th International Congress of Eye Research, San Francisco CA, September 1988.

- Jester JV, Cavanagh HD, **Mathers WD**, Lemp MA: "'In vivo' cell responses to injury using confocal microscopy." 8th International Congress of Eye Research, San Francisco CA, September 1988.

- **Mathers WD**, Lemp MA, Cavanagh HD: "Corneal epithelial morphology of contact lens wearers." International Society for Contact Lens Research, Koloa, Kanai HI, August 31-September 3, 1988.

- Cavanagh HD, Jester JV, **Mathers WD**, Dilly PN, Lemp MA: "Real time in vivo corneal cellular morphology: Confocal tandem scanning microscopy." International Society for Contact Lens Research, Koloa, Kanai HI, August 31-September 3, 1988.

- **Mathers WD**: "Non-perforating eye injuries: Corneal abrasions and foreign bodies", and "Ocular history and physical examination." Ophthalmology Workshop for the Emergency Physician, Program Director. Georgetown University, Washington DC, September 17, 1988.

- Lemp MA, **Mathers WD**, Cavanagh HD: "Ocular surface disease: Pathogenesis and management." Course presented at American Academy of Ophthalmology, Las Vegas NV, October 12, 1988.

- **Mathers WD**: "Ocular allergy and contact lens-induced GPC." Center for Sight/Fall Symposium - Recent Advances in Immunopathologic Diseases of the Eye. Georgetown University, Washington DC, October 19, 1988.

- **Mathers WD**: "Specular microscopy and methods of office corneal examination." Greenbrier Postgraduate Course: Office-Based Ophthalmology, White Sulfur Springs WV, October 21-22, 1988.

1989

- **Mathers WD**: "The effect of contact lenses on the eyelids," and "Changes in the ocular surface with contact lens wear." CLAO Annual Meeting, New Orleans LA, January 19, 1989.

- **Mathers WD**: "Primary anterior segment repair in ocular trauma." Spring Clinical Conference: Comprehensive Management of the Ocular Trauma Patient. Georgetown University, Washington DC, March 11, 1989.
- **Mathers WD**: "The treatment of blepharitis." Washington Ophthalmological Society, March 21, 1989.

- **Mathers WD**: "Ophthalmic history taking." 10th Annual Review Course and Continuing Education Program for Ophthalmic Medical Personnel. Georgetown University, Washington DC, May 11-13, 1989.

- Visiting Professor, Medical College of Virginia, Richmond VA, May 1989.

- **Mathers WD**: "Blepharitis: New approaches to an old problem." 27th Annual Residents Day and Alumni Conference, Georgetown University, Washington DC, June 10, 1989.

- **Mathers WD**: "External disease lecture." 23rd Annual Washington DC Post-Graduate Course in Ophthalmology, July 24-25, 1989.

- **Mathers WD**: "Lid effects on the ocular surface." American Academy of Ophthalmology, New Orleans LA, October 30, 1989.

- Lemp MA, **Mathers WD**: "Ocular surface disease: Pathogenesis and management." American Academy of Ophthalmology, New Orleans LA, November 1, 1989.

- **Mathers WD**: "Infections, contact lenses, and the eye: Recent successes and controversies." Fall Clinical Conference, Course Director. Georgetown University, Washington DC, November 4, 1989.

1990

- Mathers **WD**: "Blepharitis concepts." Washington Ophthalmic Society, January 30, 1990.

- **Mathers WD**: "Confocal microscopy of the human eye." Contact Lens Symposium, International Congress of Ophthalmology, Singapore, May 1990.

- **Mathers WD**, Shields WJ, Sachdev M, Jester JV: "Meibomian gland dysfunction and chronic blepharitis." Castroviejo Society, May 1990.

- Visiting Professor, University of Western Australia, Perth, Australia, May 1990.

E. **Other: Exhibits, Films, Tapes, Special Presentations Cont..**

- **Mathers WD**: "Meibomian gland morphology and function in chronic blepharitis." 28th Annual Residents and Alumni Conference, Georgetown University, Washington DC, June 1990.

- **Mathers WD**: "Eyelid disease and meibomian gland dysfunction", and "Eyelid disease and ocular surface defects." The Greenbrier Course, White Sulfur Springs WV, October 1990.

- **Mathers WD**: "Variations in surface cell morphology with different types of contact lenses." Institute for Contact Lens Research, Monte Carlo, 1990.

- Visiting Professor, University of Connecticut, Hartford CT, December 1990.

1991

- Mathers WD, Sachdev M: "Ocular effects of Accutane use in humans" and "The objective analysis of meibomian gland function in blepharitis." All India Ophthalmological Society, Bangalore, India, January 1991.

- Mathers WD: "Lid disease and dry eye." Sjögren Society Meeting, Washington DC, April 1991.

- Mathers WD: "Meibomian gland dysfunction and its role in maintaining tear osmolarity in chronic blepharitis." Virginia Society of Ophthalmology, Reston, VA, May 1991.

- Mathers WD: "History taking." 12th Annual Review Course and Continuing Education Program for Ophthalmic Medical Personnel, Georgetown University, Washington DC, May 1991.

- Mathers WD: "Corneal astigmatism following cataract surgery: Control and prevention." Maryland Society of Eye Physicians and Surgeons, Baltimore MD, September 1991.

- Visiting Professor, Val de Grace Hospital, Paris, France, September 1991.

- Mathers WD: "Skin and mucous membrane disease." American Academy of Ophthalmology, October 1991.

- Mathers WD: "Eyelid, Cornea and Tear Physiology Related to Contact Lens," "Solutions,

- Mathers WD : Care Regimens, Patient Education and Follow-Up," "Therapeutic Contact Lenses." CLAO Regional Basic Contact Lens Seminar, Dallas, TX, November 1991.

1992

- Mathers WD: "Meibomian gland dysfunction and giant papillary conjunctivitis." CLAO Annual Meeting, Las Vegas NV, January 1992.

- Mathers WD: "Meibomian gland dysfunction and the sebaceous gland analogy." Iowa Dermatologic Society Meeting, Iowa City, Iowa, September 19, 1992.

- Mathers WD: "DK and Corneal Hypoxia." Iowa Optometry Meeting, October 1992.

- Mathers WD: "Patient Compliance: Will They or Won't They?" American Academy of Ophthalmology, November 1992.

1993

- Mathers WD: "The Red Eye." Refresher Course for Family Physicians, Department of Family Practice, University of Iowa Hospital, March 1993.

- Mathers WD: "DK and Corneal Hypoxia." Iowa Optometric Association, October 1993.

- **Mathers WD**: "Imaging of the Cornea." American Academy of Ophthalmology, 1993.

- **Mathers WD**: "Confocal Imaging of Acanthamoeba Keratitis." Ocular Microbiology and Immunology Group, American Academy of Ophthalmology, November 1993.

- **Mathers WD**: "The Interaction of the Contact Lens and the Tear Film: Wichterle's Days of Contact Lens." Prague, Czechoslovakia, October 1993.

1994

- **Mathers WD**: "Evaporation from the Contact Lens Surface." Las Vegas, Nevada, January 1994.

- **Mathers WD**: "Imaging the Cornea and the Contact Lens." Contact Lens Society of America Meeting, Phoenix, Arizona, March 1994.

- **Mathers WD**: "Tear Film Evaporation and the Contacts Lens." Touhy Lectureship, Contact Lens Society of America Meeting, March 1994.

- **Mathers WD**: "Evaporation and Tear Film in Lacrimal Insufficiency." ARVO, May 1994

- **Mathers WD**: "Confocal Microscopy in Ophthalmology," and "Meibomian Gland Dysfunction and the Dry Eye." Resident Alumni Day Guest Speaker, Department of Ophthalmology, University of Washington, Seattle, June 1994.

- **Mathers WD**: "Blepharitis and Meibomian Gland Dysfunction." Iowa Eye, June 1994.

- **Mathers WD**: "Evaporation from the Contact Lens." International Congress of Ophthalmology, Toronto, June 1994.

- **Mathers WD**: Contacts lenses and Acanthamoeba infections, ECLSO, Alicante, Spain, September 1994.

1995

- **Mathers WD**: Corneal Physiology Symposium: Corneal Epithelium in Health and Disease, "The Adnexa, the Tears and the Epithelium: A Story of Close Quarters and Toxic Waste." Contact Lens Society of America Annual Meeting, Los Vegas, Nevada, January, 1995.

- **Mathers WD**: Castroviejo Society Symposium: Imaging the Anterior Segment, "Confocal Microscopy I: Optics and Clinical Indications." Contact Lens Society of Americal Annual Meeting, Los Vegas, Nevada, January, 1995.

- **Mathers WD**, Nelson JD: Anatomy & Pathology/Cornea, "Diagnosis of the Dry Eye." Moderators at Association for Research in Vision and Ophthalmology, Ft. Lauderdale, May 1995.

- Sutphin JE, Elgin RG, **Mathers WD**, Winchester K: "Confocal microscopy of infectious crystalline keratitis: a case study." Poster presented at Association for Research in Vision and Ophthalmology, Ft. Lauderdale,Florida, May 1995.

- **Mathers WD**: "Confocal Microscopy: The New Paradigm for Corneal Disease." Simpósio Internacional de Lentes de Contato e Córnea (International Symposium on Cornea and Contact Lens),Goiânia, Brazil, May 1995.

- **Mathers WD:** "Contact Lenses and Evaporation from the Ocular Surface." Simpósio Internacional de Lentes de Contato e Córnea (Intnl Symposium on Cornea and Contact Lens), Goiânia, Brazil, May

- **Mathers WD**: "Dry Eye and Its Causes." Simpósio Internacional de Lentes de Contato e Córnea (International Symposium on Cornea and Contact Lens), Goiânia, Brazil, May 1995.

- **Mathers WD**, Sutphin JE, Elgin R, Folberg R: "The Iowa Epidemic: Unmasking Acanthamoeba Keratitis." The Annual Iowa Meeting, Iowa City, IA, May 1995.

- **Mathers WD,** Lane J: "The Effect of Age on Tear Flow Measurements and Meibomian Gland Function." The Association for Research in Vision and Ophthalmology, Ft. Lauderdale, Florida, May 1995.

- **Mathers WD**: "Acanthamoeba Keratitis and the Contact Lens." XXV Congress of the ECLSO, Clermont-Ferrand, France, September 1995.

- **Mathers WD:** "Blepharitis and the Dry Eye." Joint Commission on Allied Health Personnel In Ophthalmology, Atlanta, GA, October 1995.

- Brown J, **Mathers WD**, Sutphin JE: "Oral Cyclosporin for High Risk Cornea Transplants." Poster presentation, American Academy of Ophthalmology Meeting, Atlanta, GA, 1995.

1996

- **Mathers WD**: "A New Model for Tear Film Function in Meibomian Gland Dysfunction, Dry Eye and Normal Eyes." 1996 CLAO Annual Meeting, Las Vegas, Nevada, Feb. 3, 1996.

- **Mathers WD**: "Confocal Microscopy of the Human Tear Film." 1996 CLAO Annual Meeting, Las Vegas, Nevada, Feb. 1, 1996.

- **Mathers WD**: "Confocal Images of the Human Tear Film and Their Correlation with Tear Function." World Congress on the Cornea IV, Orlando, Florida, April 17, 1996.

- Lane JA, **Mathers WD**: "The Effect of Digital Expression of the Meibomian Glands on the Lipid Layer of the Tear Film and Evaporation rate." Poster presentation, 1996 Association for Research and Vision in Ophthalmology Annual Meeting, Ft. Lauderdale, Florida, May, 1996.

- **Mathers WD,** Lane JA, Zimmerman MB: "The Physiological Assessment of the Human Tear Film Using Confocal Microscopy and Its Correlation with Ocular Pathology." Poster presentation, 1996 Association for Research in Vision and Ophthalmology Annual Meeting, Ft. Lauderdale, Florida, May, 1996.

- **Mathers WD**: "Advances in Diagnosis and Treatment of Corneal Transplant Rejection" presented at the XII Brazilian Congress of Ophthalmology Prevention of Blindness Meeting, Sao Paulo, Brazil, September, 1996.

- **Mathers WD**: "Tear Film and Lacrimal Gland Function and Contact Lenses" presented at the XII Brazilian Congress of Ophthalmology Prevention of Blindness Meeting, Sao Paulo, Brazil, September, 1996.

- **Mathers WD**: "Complications of Contact Lenses" presented at the XII Brazilian Congress of Ophthalmology Prevention of Blindness Meeting, Sao Paulo, Brazil, September, 1996.

- **Mathers WD**: "A Look into the Future of Cornea" presented at the Iowa Eye Association Alumni Meeting, Iowa City, Iowa, September 19, 1996.

- **Mathers WD**: "Alternative Ophthalmic Imaging" presented at the Ophthalmmic Photographers' Society 27th Annual Educational Program, Chicago, October, 1996.

- **Mathers WD**: Discussant: Manuscript "Instant Diagnosis of Bacterial, Fungal, Amoebic and HSV Keratitis with the White Light Confocal Microscope" submitted by Dr. Stephen Charles Kaufman, American Academy of Ophthalmology Annual Meeting, Chicago, October, 1996.

- **Mathers WD**: "Ocular Infections and Cellulitis" presented at the Clinical Lecture Series for Family Practice Residents and Faculty, Iowa City, Iowa, November 6, 1996.

- **Mathers WD**: "Lacrimal Gland, Tear Film, and Dry Eye Syndrome" presented as keynote address at the Second International Congress on Lacrimal Gland, Tear Film, and Dry Eye Syndromes: Basic Science and Clinical Relevance, Southampton Parish, Bermuda, November, 1996.

1997

- **Mathers WD**: "Confocal Microscopy of *Acanthamoeba* Keratitis: Human and Animal Studies" presented at the Contact Lens Association of Ophthalmologists annual meeting, Las Vegas, January, 1997.

- **Mathers WD**: "The Dry Eye and Contact Lenses, Therapeutic Contact Lenses" presented at the Contact Lens Association of Ophthalmologists, XXI Pan American Congress, Cancun, Mexico, May, 1997.

- **Mathers WD**: "Confocal Microscopy: In Pursuit of Resolution" dialogue with Drs. James D. Auran, Charles J. Koester, Raine K. Mustonen, Marguerite B. McDonald reprinted in Eye World 2(5):14-17, May 1997.

- **Mathers WD**: "Considerations in Astigmatism after PKP" presented at the Iowa Eye Association Alumni meeting, Iowa City, Iowa, June, 1997.

- **Mathers WD**: "Complications of Contact Lens Wear" presented at the Japan Contact Lens Society 40th Annual Meeting, Osaka, Japan, June, 1997.

1998

- **Mathers WD**: Invited Lecture as Visiting Professor at University of Oregon, Portland, February, 1998.

- **Mathers WD**, Folberg R, Sutphin JE, Allen R, Stone E, Wilson M: "Acanthamoeba Keratitis: New Approaches to Diagnosis." Poster presentation at the XXVIII International Congress of Ophthalmology, Amsterdam, June, 1998.

- **Mathers WD:** "Introduction: Confocal Microscopy in the Eye--Applications." presented at the XIII International Congress of Eye Research, Paris France, July, 1998.

- **Mathers WD**: "Current Limitation to the Resolution of Confocal Microscopy." presented at the XIII International Congress of Eye Research, Paris France, July, 1998.

- **Mathers WD**: "Technical Aspects of In Vivo Confocal Image Capture." Poster presentation at the XIII International Congress of Eye Research, Paris France, July, 1998.

- **Mathers WD**: "Status of Acanthamoeba Detection with Confocal Microscopy." Poster presentation at the XIII International Congress of Eye Research, Paris France, July, 1998.

- Salomao DR, **Mathers WD**, Sutphin JE, Cuevas KH, Folberg R: "Cytologic Changes in the Conjunctiva Mimicking Malignancy After Topical Mitomycin-C Chemotherapy." platform presentation at the American Academy of Ophthalmology annual meeting in New Orleans, November, 1998.

1999

- **Mathers WD**, Nelson SE., Folberg R: "Confirmation of Confocal Microscopy Diagnosis of Acanthamoeba Keratitis Using Polymerase Chain Reaction Analysis" poster presentation at Association for Research in Vision and Ophthalmology Annual meeting in Fort Lauderdale, FL May, 1999

- **Mathers WD**, Lane, JA: "The relationship between Sex Hormone levels and Tear Function in Women with Sjogren's Syndrome" poster presentation at Association for Research in Vision and Ophthalmology Annual meeting in Fort Lauderdale, FL : May, 1999

- Lane JA, **Mathers, WD**: " The Relationship Between Sex Hormones and Meibomian Gland Function in Men and Women" poster presentation at Association for Research in Vision and Ophthalmology Annual meeting in Fort Lauderdale, FL . May, 1999

- **Mathers, WD** "Corneal Research at The Casey Eye Institute" presented at Oregon Association of Ophthalmology meeting, Portland, OR. May 1999

- **Mathers, WD** "New Treatments of Dry Eye" slide presentation at Columbia Gorge Seminar for Cataract, Cornea & Refractive Surgery, Stevenson, WA. Jul. 1999

- **Mathers, WD** "Management of Surface Disease/Keratitis" slide presentation at Columbia Gorge Seminar for Cataract, Cornea & Refractive Surgery, Stevenson, WA. Jul. 1999

- **Mathers, WD** "Confocal Examination of the Tear Film" Presented at Japan Contact Lens Society 42nd Annual Meeting, Yokohama, Japan Jul. 1999

- **Mathers, WD** "New Methods of Diagnosing Acanthamoeba Keratitis " Slide presentation at Japan Contact Lens Society 42nd Annual Meeting, Yokohama, Japan Jul. 1999

- **Mathers, WD** "Extended Wear Use Issues For Contact Lens Patients" Slide presentation at the XXII Congress of the Pan-American Association of Ophthalmology, Orlando, FL. Oct. 1999

- **Mathers, WD** "Dry Eye Syndrome" Slide presentation for the Willamette Ophthalmic Society, Salem, OR. Nov. 1999

- **Mathers, WD** "Measurement of the Tear Film: A Review" Jonathan Kersley Guest Lecture Presented at The Medical Contact Lens and Ocular Surface Association Annual Meeting, London, Dec. 1999

2000

- **Mathers, WD**. "Why the Eye Becomes Dry" Slide presentation for Beren's Memorial Lecture at the Contact Lens Association of Ophthalmologists Annual Meeting, Las Vegas, NV. Jan. 2000

- **Mathers, WD** "Dry Eye and Sjogren's Syndrome-Why People Get Dry Eye" Presented at Healthy Talks-Focus on Eye Care ,OHSU, Portland, OR. Apr. 2000

- **Mathers WD**, Dolney AM " Objective Demonstration of Tear Film Stimulation with Oral Pilocarpine in Dry Eye Patients" poster presentation at Association for Research in Vision and Ophthalmology Annual meeting in Fort Lauderdale, FL . May, 2000

- **Mathers, WD** "Acanthamoeba Keratitis: Diagnosis and Management" slide presentation at Columbia Gorge Seminar for Cataract, Cornea & Refractive Surgery, Stevenson, WA. 7/00

- **Mathers, WD** "Blepharitis and Dry Eye" slide presentation at Columbia Gorge Seminar for Cataract, Cornea & Refractive Surgery, Stevenson, WA. Jul. 2000

- **Mathers, WD.** "Laser Correction and Refractive Errors" slide presentation at Portland Rotary Club meeting, Portland, OR. Aug. 2000

- **Mathers, WD**. "Why the Eye Becomes Dry" slide presentation at Oregon Ophthalmic Alumni Association meeting, Portland, OR. Sept. 2000

- **Mathers, WD** " Meibomian Gland Disease: An Overview" slide presentation at International Congress of Eye Research, Santa Fe, NM Oct. 2000

- **Mathers, WD** "Managing Contact Lens Complications" PowerPoint presentation at The Resident Course on Optics, Refraction and Contact Lenses, CEI Portland, OR. Oct. 2000

- **Mathers, WD** " The Use of Confocal Microscopy in Refractive Surgery" Powerpoint presentation at Collaborative Ophthalmology Rounds at The Devers Eye Institute Portland, OR. Nov. 3, 2000

2001

- **Mathers, WD** " Applications of Confocal Microscopy in Refractive Surgery" Presentation for The Portland Metropolitan Optometrics Society Portland, OR. Jan 2001

- **Mathers, WD** "Opticians Association Of Oregon, Optical Odyssey-2001" Presentation for Refractive Surgery and the role of the Optician. Casey Eye Institute March 2001

- **Mathers WD**, "National Eye Institute: Dry Eye Workshop". Conducted at the Association for Research in Vision and Ophthalmology Annual meeting in Fort Lauderdale, FL. May, 2001

- **Mathers, WD**, "Vision 2001: A Comprehensive Ophthalmology Update, Dry Eye in LASIK Patients", Presentation at Casey Eye Institute, OHSU, September 2001.

- **Mathers, WD**, "Confocal Microscopy, Theory and Applications. How you could use this instrument."Presentation at Brazilian Congress of Ophthalmology, Sao Paulo, Brazil, September 2001

- **Mathers, WD**, "Dry Eye Theory and Practice." Presentation at Brazilian Congress of Ophthalmology, Sao Paulo, Brazil, September 2001

- **Mathers, WD**, "Confocal Microscopy, Theory and Application: How you could use this instrument" Presentation at Brazilian Congress of Ophthalmology, Sao Paulo, Brazil, September 2001

- **Mathers, WD**, "Acanthamoeba Keratitis" Presentation at Brazilian Congress of Ophthalmology, Sao Paulo, Brazil, September 2001

- **Mathers, WD**, "Contact Lens Update, Complications, Projections for the Future" Presentation at Brazilian Congress of Ophthalmology, Sao Paulo, Brazil, September 2001

- **Mathers, WD**, "Tear Film Examination, What is useful to measure and why" Presentation at Brazilian Congress of Ophthalmology, Sao Paulo, Brazil, September 2001

2002

- **Mathers, WD**, "Dry Eye Perspective, How physiologic tests relate to ocular surface disease." Presentation at New England Ophthalmological Society, Boston, MA, April 2002.

- **Mathers, WD**, "Chronic external disease can be acanthomoeba." Presentation at New England Ophthalmological Society, Boston, MA, April 2002.

2003

- **Mathers, WD**, "The View From Within: In Vivo Confocal Microscopy of Leukocyte-Endothelial Dynamics in Patients with Uveitis or Scleritis." Presentation at ARVO Annual Meeting, Fort Lauderdale, Florida, 2003.

- **Mathers, WD, "**Long Term Changes in Lacrimal Gland Gene Expression Following Corneal Trauma." Presentation at ARVO Annual Meeting, Fort Lauderdale, Florida, 2003.

- **Mathers, WD**, "Possible Increased Leukocyte Adhesion in Patients Who Wear Overwear Soft Contact Lenses or Wear Contace Lenses with Lower Dk Values". Presentation at ARVO Annual Meeting, Fort Lauderdale, Florida, 2003.

- **Mathers, WD**, "Acanthamoeba Sensitivity Testing Results for Various Amobacidal Medications and Concentrations." Presentation at ARVO Annual Meeting, Fort Lauderdale, Florida, 2003.

- **Mathers, WD**, "Leukocyte Dynamics and Confocal Microscopy of the Human Conjunctiva." Presentation at X Biennial Western Eye Research Conference, Laguna Beach, California, September 2003.

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Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of	:	
Sharon F. Kleyne	:	Group Art Unit: 1619
Serial No. 09/614,790	:	Examiner: Michael Willis
Filed: July 12, 2000	:	Tel. No. (703) 305-1679
For a Patent for	:	
METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE		

DECLARATION OF DR. DARWIN J. LIAO
37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

1. I, Darwin J. Liao, MD, MPH, am a comprehensive ophthalmologist and a partner in Seattle Eye MDs, a full service ophthalmology clinic in Seattle, Washington. Neither I nor anyone associated with Seattle Eye MDs is affiliated with or receives any compensation from Sharon Kleyne (the inventor of the present application) or from her company, Rogue Valley Natural Springs, Inc. I have met Sharon Kleyne on several occasions.

2. On one occasion, I met Ms. Kleyne at an ophthalmology trade show that I was attending. At that trade show, she told me about her product, Nature's Tears™, and explained how it differed from all other products that are available for alleviating symptomatic discomfort for individuals suffering from dryness of the eyes.

3. Sharon Kleyne explained that other products, such as artificial tears or other formulations in the form of eye drops, deliver a quantity of fluid that is greater than the volume of the tear film. This results in a washing away of the tri-laminar tear film and replacement of this tear film by a mono-layer containing whatever fluid was delivered to the eye. It then takes some time and many blinks for the eye to rid itself of this foreign and unnatural fluid and to reconstruct the normal three-layered tear film. The key, according to Ms. Kleyne, is to provide an aqueous fluid in an amount that is sufficient to re-hydrate the tear film and that leaves the already present tear film in place on the surface of the eye. I have since evaluated Ms. Kleyne's product, Nature's Tears, in my ophthalmology practice.

4. In my practice, I care for many patients who suffer from dry eyes. I have recommended and prescribed to my patients many different therapies for symptomatic relief from dry eye.

5. My experience with eye drop therapies has not been entirely successful. Many of my patients have complained that it is difficult to administer eye drops and that their eyes feel worse a few minutes after using eye drops. This problem of difficulty in administration of eye drop therapy occurs very frequently and is a serious issue in elderly patients and in patients with motor difficulties. Because of these and other problems with eye drops, I have experienced problems in patient compliance as many of my patients apply the eye drops less frequently than recommended or discontinue use of them completely.

6. In my practice, I now dispense to my dry eye patients Nature's Tears, the product sold by Ms. Kleyne's company and which is described and claimed in this patent application. Nature's Tears delivers a very small quantity of aqueous fluid which is sufficient to moisturize the surface of the eye and which leaves the tri-laminar tear film intact on the eye. It does this by delivering water to the eye in the form of a mist.

7. The results I have obtained with Nature's Tears have been outstanding. I no longer receive complaints about discomfort upon or after application or about difficulty in applying eye moisturizing therapy. Many of my patients have even commented to me about how good their eyes feel when they use Nature's Tears. I find this to be very significant because I rarely, if ever, receive comments from my patients about a product when they are satisfied with a product. Rather, comments from patients usually are received only when they are dissatisfied with something. More important than receiving good comments, however, is the fact that my patients continue to use Nature's Tears because it is effective in reducing symptoms of dry eye and the mist is very easy and comfortable to apply to the eye. My elderly patients, many of whom suffer from secondary eye conditions due to eyelid laxity and other such disorders, and my patients with motor difficulties find the Nature's Tears mist very easy to apply. Therefore, I no longer have problems with patient compliance with dry eye topical therapy now that I dispense Nature's Tears.

8. Nature's Tears is now my primary treatment of choice for all my dry eye patients and I also use it as an adjunct therapy for all secondary causes of dry eye, such as those cases of dry eye that require pharmaceutical or surgical intervention.

9. Like many of my patients, I also suffer from symptomatic discomfort due to dry eye. In the past, I have used various eye drop formulations to relieve my dry eye symptoms, but I no longer do so. Now, when my eyes feel dry, I apply Nature's Tears. Like my clients, I have found Nature's Tears to be far more effective in relieving my discomfort due to dry eye than are eye drops.

10. It is my feeling that Nature's Tears is a revolutionary product in the symptomatic treatment of dry eye. It maintains the integrity of the tear film and provides a previously

unrealized degree of comfort when used by an individual who is experiencing symptoms of dry eye.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1-9-04
Date

Darwin J. Liao, MD, MPH

OIPE
MAY 1 3 2005
PATENT & TRADEMARK OFFICE

Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Sharon F. Kleyne	:	Group Art Unit: 1617
Serial No. 09/614,790	:	Examiner: Shengjun Wang
Filed: July 12, 2000	:	Tel. No. (571) 272-0632
For a Patent for METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	

SECOND DECLARATION OF DR. WILLIAM D. MATHERS
37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

1. I, William D. Mathers, MD, am a Professor of Ophthalmology at Oregon Health and Science University – Casey Eye Institute in Portland Oregon. I filed a previous Declaration in relation to this application in January 2004. A copy of my curriculum vitae was attached to my previous Declaration. My previous Declaration also briefly described my relationship with Rogue Valley Natural Springs, Inc., the assignee of this application. I am familiar with the prosecution of this application in the U.S. Patent Office.

2. I am submitting this Declaration to provide additional evidence to that which has already been submitted to establish that this invention is not obvious. In particular, I am submitting this Declaration to demonstrate that this invention provides a solution to a long-

standing problem pertaining to the treatment of patients suffering from symptoms of dry eyes, the problem of a lack of patient compliance in the use of topical dry eye therapies.

3. It has long been recognized in the field of ophthalmology that many, if not most, patients requiring the administration of eye drops fail to comply in part or at all with the recommendations of their treating physician. Attached to this Declaration as Exhibit I is an article, Winfield, et al, "A Study of the Causes of Non-Compliance by Patients Prescribed Eyedrops", British Journal of Ophthalmology, 74:477-480 (1990). This article discusses the problem of the lack of patient compliance in the use of eyedrops and addresses several causes for this lack of compliance.

4. The data disclosed in the Winfield et al article shown in Table 1 on page 478 show that only 64% of patients use eye drops as directed and, even more striking, that only 62% of patients administer their own drops. As stated in the first full paragraph on page 478, second column: "Over a third of patients did not administer their own drops regularly, with 21% always using assistance. . . . In total, 57% of patients admitted having some difficulty administering their drops."

5. Table 2 on page 478 presents the main problems that patients have with administering eye drops. As stated on page 478, second column, first full paragraph: "Discussion with patients indicated that lack of confidence was a major factor, particularly fear of prodding the eye. As a result the bottle was often held too far from the eye, making the aim more difficult and encouraging the blink reflex. Older patients experienced physical problems in

raising the arm, tilting the head, and in holding and squeezing the bottle." Table 3 on the bottom of page 478 shows that many patients do not aim eyedrops well.

6. On page 479, first column, last paragraph, Winfield et al summarize their conclusions: "From this work it appears that we have identified two interrelated problems with the self administration of eyedrops: firstly, the lack of physical acuity, and secondly the inability to aim adequately." On page 479, second column, last paragraph, Winfield et al conclude that: "Apart from the evidence we have produced, demographic trends indicate that the number of patients experiencing difficulty will increase rather than decrease. Difficulty in administering drops increases with age. Projections indicate that the population of 85 years old and above will increase by a third over the next 10 years."

7. A recent search on the PubMed database shows that the problem of lack of patient compliance in the use of eyedrops for the treatment of symptoms relating to dry eyes is one that has been recognized by researchers in the field of ophthalmology for quite some time. Attached to this Declaration as Exhibit 2 is a PubMed search that looked for articles dealing with subjects related to the Winfield article. The search produced a listing of 114 articles, many of which deal with the problem of lack of compliance, with the difficulty in administering eyedrops, or with means for facilitating eyedrop administration. From a reading of the titles in the search, it appears to me that articles 1-14, 16, 18-20, 23-26, 28-29, 31-33, 35, 44, 46-48, 60-62, 78-80, 83, 86, 91, 93, 100, 101, 106, 108, 109, 113 deal with problems relating to the administration of eyedrops, with the vast majority of these articles dealing with the problem of lack of patient compliance.

8. Attached to this Declaration as Exhibit 3 are abstracts of articles numbered 2, 5, 7, 20, 23, 33, 46, and 62 of the PubMed search. These articles deal with various aspects of the problem of lack of patient compliance and make clear that the issue of non-compliance with eyedrops is a long standing one due to difficulties that patients have in self-administration.

9. In my Declaration of January 2004, I submitted data from a survey of 39 patients who either had dry eye (33) or had other reasons for needing an eye care product for moisturizing the eye (6). Of these 39 patients, 35 (89%) had previously used other eye care products and of these 72% (25) had experienced favorable results with those products. The patients were given Nature's Tears to use freely for 2 weeks, as needed. Telephone interviews were conducted after the two week period. Nature's Tears is a commercial embodiment of the invention with which a user moisturizes his/her eyes by spraying a mist of water towards the face. The use of Nature's Tears does not require an individual to aim precisely to the eye and does not require an individual to bend the neck so as to look upward, as is required when moisturizing the eye with eyedrops.

10. Of the 39 patients, 83% (32) found Nature's Tears to be more convenient than the other products that they had used (eyedrops). Only 8% (2) found Nature's Tears to be less convenient, and 8% (2) found the convenience of Nature's Tears to be about the same. One patient in the survey stated that she preferred Nature's Tears over eyedrops because she has arthritis. Due to the debilitating condition in her hands, she found Nature's Tears to be much easier to use.

11. In January 2004, Dr. Darwin Liao, an ophthalmologist in Seattle, Washington, submitted a Declaration. In the Declaration of Dr. Liao, he testified that he cares for many patients who suffer from dry eyes and that his experience with conventional eyedrop therapies had not been entirely successful. He testified that many of his patients have complained of difficulty in the administration of eyedrops and that this problem of difficulty in administration of eyedrop therapy occurs very frequently and is a serious issue in elderly patients and in patients with motor difficulties. Dr. Liao summarized his experience with conventional eyedrops by stating that he had experienced problems in patient compliance because many of his patients applied the eye drops less frequently than recommended or discontinued use of them completely.

12. Dr. Liao then testified that the results that he has obtained with Nature's Tears have been outstanding. He stated that he no longer receive complaints about discomfort upon or after application or about difficulty in applying eye moisturizing therapy. Many of his patients have even commented about how good their eyes feel when they use Nature's Tears. Significantly, Dr. Liao testified that his patients continue to use Nature's Tears because it is effective in reducing symptoms of dry eye and the mist is very easy and comfortable to apply to the eye. His elderly patients, many of whom suffer from secondary eye conditions due to eyelid laxity and other such disorders, and his patients with motor difficulties find the Nature's Tears mist very easy to apply. Therefore, Dr. Liao concluded, he no longer has problems with patient compliance with dry eye topical therapy in his ophthalmology practice now that he dispenses Nature's Tears.

13. The references referred to above establish that the problem of lack of patient compliance with present methods of moisturizing the eye has been a longstanding problem and that the solution to this problem has proven to be evasive. The data from my study of 39 patients described in my previous Declaration of January 2004 and the testimony in the Declaration of Dr. Darwin Liao also of January 2004 establish that the use of Nature's Tears eye mist increases patient compliance regarding the use of eye moisturizes and that the present invention provides a solution to the longstanding problem of lack of patient compliance with eye moisturizing products.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

5/5/2005
Date

William D. Mathers, MD

Attachments: (1) Exhibit 1: Winfield, et al, British Journal of Ophthalmology, 74:477-480 (1990)
(2) Exhibit 2: PubMed search listing 114 articles
(3) Exhibit 3: Selected abstracts (8) from articles listed in PubMed search

British Journal of Ophthalmology, 1990, 74, 477–480

A study of the causes of non-compliance by patients prescribed eyedrops

A J Winfield, D Jessiman, A Williams, L Esakowitz

Abstract

An investigation into the causes of non-compliance by patients using eyedrops has been undertaken by questionnaire, ability tests, and by tests on eyedrop bottles. The results indicate a high prevalence of non-compliance, compounded by an inability adequately to instil a drop into the eye. About half the patients had difficulty aiming the drop, and other problems including squeezing the bottle, blinking, and seeing the tip of the bottle. Ability tests included a measurement of the grip strength of patients to complement measurement of the force required to expel a drop from a bottle. Some patients, particularly those with arthritis, could not generate enough force to squeeze a bottle. These same patients also had difficulty with the other movements required to administer drops. While some attempts have been made to produce devices to assist with eyedrops which can improve the aim of the patient, none give assistance in expelling a drop. An additional problem found was the reluctance of patients to admit to medical staff that they experienced any difficulty with their drops.

It is well established that complience of patients with a prescribed treatment is often inadequate. This may be due to a complex interaction of factors, prime among them being lack of knowledge, inability, or disinterest. Eye preparations are no exception.[1] Several teams have undertaken studies in an attempt both to enumerate the extent of the problem and to understand its origin.

One approach has been to use a special drop bottle with an electronic device to record drop administration. In one study[2] such a device showed that 41% of patients missed six or more doses over a 30-day period. A similar study[3] found that over half the patients missed 20% of their prescribed doses. Other studies have relied on interview[4,5] and observation[6,7] and have produced similar results. All these studies were undertaken with patients regularly using eyedrops for glaucoma, one of them[6] indicating that 13% of patients observed were unable to place drops in both eyes after several attempts.

Interviewing patients using eyedrops after cataract surgery[8,9] revealed a similar range of problems and non-compliance. Other workers have also demonstrated problems with drop size, reporting a wide variation in drop size from commercial eye drops[10] and variation in the number of drops actually expelled by patients.[7]

Collectively these studies have shown that many patients have experienced difficulties in self-administration of eyedrops. Some possible reasons for this have been elucidated and some 'at risk' groups identified.[11] Many of the problems appear to be physical, that is, related to the ability of the patient to aim a drop accurately into the conjunctival sac. To help them several devices have been used and reported on. Letocha[12] reviewed those available in 1985, which all attempted to help the patient aim more effectively. One was a plastic support device,[13] another consisted of modified sunglasses,[14] while another had a system of mirrors to help the patient see the dropper tip.[15] Later published ideas have included a modified glasses frame[16] and a cone shaped device to support and direct the dropper.[17] The reports do not indicate whether the devices were successful in achieving their objective. However, it appears that their design was based on perception of a problem rather than on detailed analysis of factors involved. In addition one manufacturer has modified the bottle to assist in expelling a drop (MSD Ocumeter).

A review[18] has reported that there are several problems which patients experience and which lead to non-compliance and concluded that it is therefore unlikely that one answer will be found. Because of the relative lack of published evidence it was decided to undertake a study aimed at elucidating the physical problems experienced by patients during eyedrop administration and from the results to derive guidance on the features required by a compliance aid.

Material and methods

Information was obtained by questioning patients, by ability tests, and by a physical evaluation of eyedrop bottles.

QUESTIONNAIRE

For the questioning the interviewer deliberately created an informal, relaxed atmosphere before asking a series of open-ended questions. Where possible, discussion was allowed to develop. In this way 200 patients attending the Eye Outpatients Department at Aberdeen Royal Infirmary were interviewed irrespective of their condition, only provided they were using eyedrops. The questions used explored the patients' knowledge of their condition and its treatment, whether their compliance was good or bad and the reasons for this, how they administered their drops, any problems encountered, and whether they would welcome a compliance aid if a suitable one was available.

ABILITY TESTS

Thirty patients in the eye surgery ward at

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Woodend Hospital, Aberdeen, agreed to undergo a series of ability tests. 10 ml bottles of hypromellose eyedrops *BNF* were used.

(1) Patients were asked to expel one drop into a preweighed vial. The increase in weight was recorded.

(2) A sheet with a series of concentric circles was used as a target. With the wrist resting on a block at a height of 4 cm the patients were asked to place a drop on the centre of the target.

(3) The patients were asked to instil a drop of hypromellose into one eye of their choice unaided. They were asked to repeat the process using the Easidrop.

(4) A dynamometer (Vigorimeter) was used to measure the pressure of squeeze exerted by finger and thumb (as on a bottle) and by the full hand.

EVALUATION OF BOTTLE

A test rig was used to measure the force required to expel drops of hypromellose from 5, 10, and 20 ml bottles (Cascelloid Division, BXL Containers Ltd). The force was applied at the midpoint on the bottle side, away from the seam. Further tests, on 10 ml bottles only, were carried out to find the effects of the bottle seam, the position of applying the force on the bottle side, the quantity of liquid in the bottle, and the storage temperature on the force required to expel a drop.

Results and discussion

QUESTIONNAIRE

The patients (average age 62, range 9–92) were being treated for glaucoma (32%), following surgery (25%), dry eye (10%), irritation and injury (10%), conjunctivitis, ulcers, and other conditions. Most knew the nature of their condition (96%) and were satisfied with their understanding of it.

Compliance patterns are shown in Table I. Any assessment of a compliance level is unreliable. By using a relaxed approach it was hoped that patients would be more open than in a more formal situation. Their readiness to admit problems and shortcomings would indicate a good level of accuracy and reliability in their responses. This being the case, 75% of patients complied well with instructions. Those who did not admitted a poor motivation owing to not understanding the function of the drops or an inability to use them. This finding suggests that if patients are well informed, as they were in this sample, their motivation is not a major problem in achieving compliance.

Table 1 Patterns of compliance in administration of eyedrops

Compliance	*Number of patients*
Used drops as directed	128 (64%)
Missed an occasional dose	24 (12%)
Missed up to two doses per week	32 (16%)
Other responses	16 (8%)
Administered own drops	124 (62%)
Did so if no one else available	34 (17%)
Always obtained assistance	42 (21%)
Had never tried self administration	16 (8%)

Table 2 Problems encountered by patients during self medication with eyedrops

Problem	*% Patients*
Directing the bottle (miss frequently)	36
Directing the bottle (miss occasionally)	13
Shaky hand	8
Squeezing the bottle	20
Blinking	12
Poor visibility of tip of dropper	13
Prodding eye with tip of dropper	9
Reading labels and identifying bottle	14

Over a third of patients did not administer their own drops regularly, with 21% always using assistance. Within this latter group, 8% had never tried self administration, 4% found it took too long, while the remaining 9% had tried but lacked the ability to place the drop in their eye. In total, 57% of patients admitted having some difficulty administering their drops. The main problems are presented in Table II. Discussion with patients indicated that lack of confidence was a major factor, particularly fear of prodding the eye. As a result the bottle was often held too far from the eye, making the aim more difficult and encouraging the blink reflex. Older patients experienced physical problems in raising the arm, tilting the head, and in holding and squeezing the bottle. Some patients found breaking the tamper-proof seal on a new bottle difficult.

The possibility of a compliance aid was welcomed by 78% of patients, but none were aware that any aids were available. Surprisingly, 72% said that the interview was the first time that they had been asked whether they had problems, while 69% said that they would not tell a doctor of their problems even if asked. This reluctance on behalf of patients was reflected in the lack of awareness among medical staff of the problems experienced by the patients.

ABILITY TESTS

(1) The weight of eyedrop solution in each vial varied from 0·03 g to 0·07 g (mean 0·39 g). Several patients expelled more than one drop.

(2) Most patients said they thought they had aimed the target well. The results are presented in Table III.

(3) Only six patients (20%) instilled a drop unaided first time. This was increased to 26 (87%) with the Easidrop device. This latter figure may be artificially high because all the patients were laid flat or almost flat so that no head-tilting was necessary.

(4) The patients had a wide range of grip strength. The pressure recorded was converted to a force based on the area of the Vigorimeter

Table 3 Accuracy of aim of patients as measured by means of target 4 cm below wrist height

Distance from centre of target	*Number of patients*
Within 1·5 cm (simulating eye)	9
Between 1·5 cm and 3 cm	14
Greater than 3 cm	7

bulb. The finger and thumb forces varied from 8·35–100·2 N, while full grip values were between 15·03 and 183·7 N. Thus the force is roughly doubled by using a full grip.

EVALUATION OF BOTTLES

Data for the average force required to expel a drop are presented in Table IV. A wide spread of results was obtained from the bottles tested, not just between bottles but also depending on the number of previous squeezes or whether it had been held in the hand for a few minutes. So at best these results can give only an indication of the forces required to expel a drop in various situations. Storage in a fridge, or pressing on the seam, increased slightly the force required. However, there was a marked increase as a bottle was progressively emptied, presumably because of the higher compressibility of air than the hypromellose solution.

The real significance of the results becomes obvious when these forces are compared with the force which the patients were able to exert. For most there was no problem, but some (approximately 13% of our sample) could not expel a drop from the bottle. (The questionnaire sample gave a higher figure of 20%.) In general these patients are those who have arthritic conditions, which also reduces their ability to raise the dropper to their eye. It may be physically impossible for this group to self-administer their drops without some additional aid.

For patients who were marginal in their ability to expel drops a second problem emerged from both the questionnaire and the ability tests. As the force being applied approached the limit of their capability, so the wobble of the hand increased. The questionnaire suggested that a further 8% were affected in this way, while observation of the practical tests suggested a much higher figure (approaching 50%). From these data it appears that 25%–50% of patients using eyedrops may have severe physical difficulty in administering them. This will manifest itself in failure to apply them, administering more than one drop (also reported by Kass,[7]), or opting out and either not trying or using a second person (30% of patients). A shaking hand affected the ability of some patients to aim accurately. The ability tests (Table III) showed that only 30% of patients could place a drop within 1·5 cm of the centre of a target (that figure taken to be the approximate size of the eye), and 47% were within 3 cm. This test was carried out in front of the patients, who could clearly see what they were doing. Corroborative evidence came from the questionnaire, where 49% admitted to missing the eye at least occasionally, and from the observation of patients placing drops in the eye, where only 20% managed it first time.

From this work it appears that we have identified two interrelated problems with the self administration of eyedrops: firstly, the lack of physical acuity, and secondly the inability to aim adequately. At present there is in the UK only one aid to assist with administering eyedrops – the Easidrop (produced by Quoteforce, UK). This screws on to the standard bottle neck until the dropper tip is level with a guide mark and, being shaped like an eyebath with cut-away sides, directs the tip of the bottle towards, but clear of, the eye. It will, therefore, improve the aim of patients – as was found in the ability tests – though it does not adequately account for gravity in a non-supine patient. Thus patients have to tilt their head back a long way, which may be difficult for those who are elderly or arthritic. It also reduces the related problem of prodding the eye and lack of visibility of the tip, but does not help in expelling a drop. Several devices aimed at improving application have been described,[12–17] but they are all concerned only with improving the aim.

Table 4 Average force required to expel a drop from an eyedrop bottle at the midpoint on the side away from the seam at room temperature (unless stated to the contrary)

Bottle/condition	Average force required (N)
5 ml	13·24
10 ml	11·76
20 ml	8·82
10 ml stored in fridge	13·22
10 ml midline on seam	12·84
10 ml half empty	17·64

Apart from the evidence we have produced, demographic trends indicate that the number of patients experiencing difficulty will increase rather than decrease. Difficulty in administering drops increases with age. Projections indicate that the population of 85 years old and above will increase by a third over the next 10 years. Unless many of the patients are able to self-administer eyedrops, very heavy demands will be placed on health service resources. Twelve years ago it was estimated that there were 100 000 cases of chronic open-angle glaucoma.[4] This figure will have increased, and it takes no account of other conditions requiring the use of eyedrops. Because of this we have taken steps to develop an aid which will assist with the problems identified – namely, aim, tilting the head, squeezing the bottle, seeing the drop approaching the eye. It will also help in breaking the tamper-proof seal. A prototype device (Fig 1) is currently undergoing evaluation with patients in both community and hospital. If any compliance aid is to be beneficial, the patient must be aware of its existence. In our questionnaire we found a very disturbing reluctance on the part of patients to

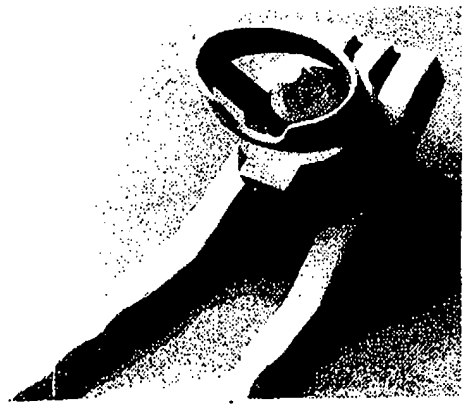


Figure 1 The Opticare compliance aid, developed as a result of this study in an attempt to ease the problems experienced in the self administration of eyedrops. The device is currently undergoing evaluation with patients.

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tell the doctor about any problems they had. Probably as a consequence of this we also found medical staff were less aware of their patients' problems than is desirable. No doubt the barrier to free communication can be broken down if doctors take a lead. There is probably also a need for an 'awareness campaign' aimed at patients, so that they do not feel guilty or inadequate because they have problems administering their eye-drops. The availability of a suitable device will also help patients achieve safe administration and improve compliance.

We gratefully acknowledge the assistance of Mr Ernest P Prebble in the design and production of the Opticare device and all medical and nursing staff and patients at the eye clinic and eye wards in Aberdeen hospitals.

The authors have no financial interest in the devices mentioned in this paper.

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[Improved eyedrop administration and compliance in glaucoma patients. A clinical study]

[Article in German]

Busche S, Gramer E.

Universitats-Augenklinik Wurzburg.

BACKGROUND: Poor compliance can be dangerous to successful medical treatment of glaucoma. Among other things one reason for non-compliance represents the inability of the patients to place drops in the eye appropriately. Therefore information regarding the patients ability to administer an eyedrop safely are a prerequisite to determining a therapy scheme which ensures the compliance of glaucoma patients. PATIENTS AND METHODS: 100 glaucoma patients on medical therapy who first presented in the outpatient glaucoma clinic of the University Eye Hospital of Wurzburg were examined by standardised questionnaire and ability tests. We evaluated: 1. Can the eyedrop administration of glaucoma patients be improved by a standardised instruction? 2. Can the eyedrop administration be improved by the use of a drop aid (Autodrop)? 3. Can the accuracy of aiming and the manual ability be evaluated with a target-test on a sheet of paper with a series of concentric circles? 4. How do patients on combined therapy distinguish between their different bottles and where is the dosage regimen noted? 5. What kind of distinguishing marks of eyedrop-bottles do the patients prefer? RESULTS: 1. Before verbal instruction 76% of the patients applied the eyedrops appropriately, after instruction 94% ($p < 0.001$) were capable. Touching the eye with the tip of the dropper was reduced significantly. Touching the eye before instruction was found in 63% of the patients, after instruction it was found in 41% ($p < 0.001$). 2. When patients used the drop aid 81% were able to place a drop in the eye appropriately. Only by 46% of the patients the Autodrop was welcomed. 3. 16% of the patients were not able to place a drop within 1.5 cm of the center of the target (according to the size of an eye). 4. 47% of the patients who use more than one eyedrop bottle admitted problems in distinguishing the bottles, only 38% of the patients read the labels. 5. 76% of the patients would prefer markable stickers of different colours for the bottom of the bottles to improve distinguishing the bottles in combined therapy. CONCLUSION: Instruction improves eyedrop administration in

18% of our patients. In combined therapy with several drugs new distinguishing marks are requested by the patients. To improve compliance combination preparations should be administered if available.

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Stack RR, McKellar MJ.

Department of Ophthalmology, Christchurch Hospital, Christchurch, New Zealand.

AIM: To determine if dark coloured tips on eye drop bottles facilitate ocular therapy. METHODS: Eye drop bottles were modified by placing sterile black tape around the bottle tip. Patients on regular timolol therapy were asked to use bottles with the modified tip for one month. They then completed a questionnaire comparing the black tips with the standard tips on the bottle they normally use. RESULTS: Eighty-eight per cent of patients found the black tipped bottles easier to use than bottles with the standard tip. Sixty-eight per cent of patients had fewer occasions on which they needed to instil a second drop and 30% of patients touched their eyelid less when using the modified bottle tips. CONCLUSION: Black coloured bottle tips aid ocular therapy. They are easier to use, result in less contact with the eye on instillation and patients note a reduction in need for a second or additional drop. This is likely to improve compliance and reduce contamination. A change in manufacturing practise should be encouraged.

PMID: 14746589 [PubMed - indexed for MEDLINE]

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1: Age Ageing. 1992 May;21(3):168-70. Related Articles, Links

Practical problems with eye-drops among elderly ophthalmology outpatients.

Burns E, Mulley GP.

Department of Medicine for the Elderly, St James's Hospital, Leeds.

Many elderly patients have eye-drops prescribed. We have examined the abilities in eye drop application of 43 consecutive outpatients aged 75 years or more who completed a questionnaire and demonstrated their technique in eye-drop application. Less than one-third of patients applied drops themselves, the rest relying on others; one-third of this group lived alone. The majority of patients experienced some difficulty with the application of their drops and it was estimated that half of those who usually applied their own treatment were unlikely to succeed in instilling a drop into the conjunctival sac. Few patients had been prescribed aids or appliances to improve their eye-drop application technique.

PMID: 1615776 [PubMed - indexed for MEDLINE]

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1: Can J Ophthalmol. 1984 Feb;19(1):2-5.

Related Articles, Links

Improper topical self-administration of ocular medication among patients with glaucoma.

Brown MM, Brown GC, Spaeth GL.

Possible sequelae of improper administration of eyedrops include treatment failure, unnecessary use of additional medications and spread of infection. To determine the extent of improper topical self-application of ocular medications, 150 patients with glaucoma who were already using eyedrops were studied. Employing their customary methods of administration 19 (13%) of the patients were unable to place drops in both eyes after one or more attempts, and 120 (80%) of the patients failed to maintain the bottle's sterility during application. No significant relation was found between performance and age, sex, educational level, visual acuity or field, intraocular pressure, length of time the patient had been using eyedrops or, among the 100 clinic patients, whether the patient had received prior instruction in their use. The 50 private practice patients had all received prior instruction, by one physician, whereas only 62% of the clinic patients had, and there had been several instructors at the clinic. Significantly more (p less than 0.05) of the clinic patients than of the private practice patients failed to wash their hands before instilling the drops (97% v. 78%) and were unable to properly instil the drops in both eyes after one or more attempts (18% v. 2%). Therefore, uniform teaching probably improves the ability of patients to topically administer ocular medication.

PMID: 6608974 [PubMed - indexed for MEDLINE]

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1: Am J Ophthalmol. 1999 Sep;128(3):368-70.

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A new eyedrop dispensing bottle.

Overaker RF, Dodge BC, Epstein DL.

Biophysics Laboratory, Department of Ophthalmology, Duke University Medical Center, Duke University Eye Center, Durham, North Carolina 27710, USA. overa004@mc.duke.edu

PURPOSE: To report a new eyedrop dispensing container that allows administration of eyedrops while the head of the patient is in the usual upright position. METHODS: An eyedrop dispensing container with a dip tube extending to the bottom, an automatic venting mechanism, and an angulated dispensing tube was developed. RESULTS: The problem of unwanted efflux of fluid was solved by incorporating the automatic venting mechanism. The final design includes an adjustable, angulated dispensing tube and "single structure" construction incorporating the cap. A removable cheek rest is also provided. The design allows eyedrops to be instilled while the patient's head is in the upright position and even when spectacles are being worn. A prototype 15-ml bottle delivered an eyedrop volume of 19.7+/-1.2 microl (mean +/- SD) (n = 75). CONCLUSION: This new eyedrop bottle should allow precise self-administration of eyedrops by a patient in front of a mirror, without a need to change head position.

PMID: 10511039 [PubMed - indexed for MEDLINE]

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1: Ophthalmology. 2003 Apr;110(4):796-800. Related Articles, Links

Inadvertent conjunctival trauma related to contact with drug container tips: a masquerade syndrome.

Solomon A, Chowers I, Raiskup F, Siganos CS, Frucht-Pery J.

Department of Ophthalmology, Hadassah University Hospital, Jerusalem, Israel. avisol@md.huji.ac.il

PURPOSE: To report the diagnosis, clinical course, and management of acute painful red eye syndrome associated with unintentional tube- or bottle-tip-induced conjunctival trauma. DESIGN: A small, noncomparative, interventional case series. PARTICIPANTS: Twelve eyes of 12 patients (8 female and 4 male, aged 21-84 years) who were urgently reported or referred with a variety of diagnoses resulting from acute onset of red, painful eye. Four eyes had corneal transplants, two were recovering from herpetic keratitis, two had undergone cataract surgery or a laser in situ keratomileusis procedure, one had a corneal neurotrophic ulcer, and one used a contact lens. All the patients had received new medications (ophthalmic ointments in nine patients, topical drops in three patients) within 1 week before onset of symptoms. INTERVENTION: Assessment of method of self-administration of topical medication, evaluation of the ocular surface lesion, and patient education. MAIN OUTCOME MEASURES: Association of patient behavior with ocular surface lesions. RESULTS: All 12 patients presented red, painful eyes, congested lower palpebral conjunctiva, epithelial conjunctival erosions, and episcleritis. In all patients, direct contact of the tube or bottle-tip with the affected area of the conjunctiva was ascertained by inspection. Instructions on proper method of drug administration and eye patching with lubrication were followed, within 2 weeks, by healing of conjunctival lesions. CONCLUSIONS: Drug containers may cause nonintentional conjunctival trauma and simulate severe ocular disorders. Physicians should be aware of this diagnosis in any case of prolonged and unexplained ocular irritation and should instruct patients as to the proper instillation of topical ophthalmic medications.

Publication Types:
- Case Reports

PMID: 12689905 [PubMed - indexed for MEDLINE]

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1: Ophthalmology. 1982 Mar;89(3):284-5. Related Articles, Links

A positioning aid for eyedrop administration.

Ritch R, Astrove E.

A device designed to improve the ability with which the patient instills eyedrops is described. This consists of a flexible, angled, vacuum-metallized polyester mirror with adhesive at one end to which a squeeze-type dropper bottle may be attached and, if desired, permanently affixed.

PMID: 7088512 [PubMed - indexed for MEDLINE]

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1: Nurs Times. 1996 Aug 7-13;92(32):36-7.

Related Articles, Links

Improving compliance with glaucoma eye-drop treatment.

Cooper J.

Many older patients attending ophthalmic out-patient clinics have been prescribed eye drops for long-term use to treat glaucoma but do not continue with their treatment. This review looks at chronic simple glaucoma, the problems of compliance with long-term medical treatment in older people and the current and future treatment of glaucoma. Recommendations are made on the nurses' role in supporting these patients.

Publication Types:

- Review
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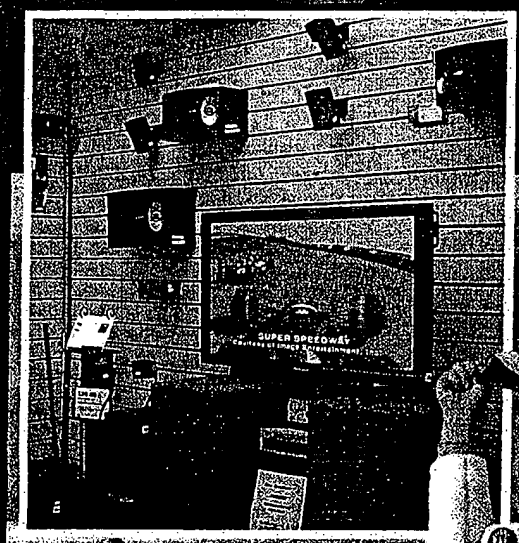
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A New Year in Military Resale

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Invention: METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE
Inventor: Sharon F. Kleyne
Application No. 09/614,790
Appeal Brief Filed April 7, 2006

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New Bio Product

Appears for Troop Health

•BAGHDAD, Iraq

In early 2003, Gottlieb Vision Group, based in Stone Mountain, Georgia, sent a care package including several cases of Nature's Tears EyeMist to the Georgia-based 221st Military Intelligence battalion deployed to the Operation Iraqi Freedom (OIF) theater. "The conditions in Kuwait/Iraq are hot, dusty, sandy and windy," wrote the battalion's Maj. Pete Van Amburgh in a letter of thanks. "Nature's Tears was a great way to get all of that out of our eyes."

Van Amburgh, who received the Bronze Star for heroism in August 2003, described how his soldiers read the directions and began "misting each other to check it out." They must have appreciated the results, because "the cases emptied in no time," he wrote.

Water comprises the majority of the earth's surface and the human body. But all water is not created equal. For biomedical use, tissue-culture grade water is often necessary. It is high-grade water with no impurities or contaminants and is pH balanced within narrow parameters. Bio-Logic Aqua Technologies has marketed a 1 oz. bottle of this water with a mist called Nature's Tears EyeMist. It can be used to soothe irritated eyes in place of eye drops, which users often find awkward to self-administer.

Eye irritation can result from smoke, smog, dust, dry air, outdoor recreation, contact lenses, allergies, even using the computer. Regular eye drops require users to tilt back their heads and lift open an eyelid. Users risk damaging their eyes with a poke from the dropper. Sometimes the product is wasted due to missed drops. Women can mar their make-up in the process. Nature's Tears EyeMist removes all of those hassles by allowing users to simply hold the eye mist 12 inches to 18 inches from their eyes and "mist" themselves.

The water, Bio-Logic Aqua, originates in deep underground springs below Oregon's Siskiyou Mountains. The water is free from pollution, heavy minerals, chemical additives, fragrances and preservatives. "We're the first water company in the world to study pharmaceutical hydrotherapy," said Sharon Kleyne, founder and chairman of the board of Bio-Logic Aqua Technologies. She spoke to *E&C News* from the company's 24-acre plant 12 miles down the Rogue River from Grants Pass, Ore.

In 1989, Kleyne discovered the natural spring at this location and confirmed its purity. She brought her discovery to William Mathers, MD, a professor at the Casey Eye Institute of Oregon Health and Science University. Dr. Mathers had long believed that pure, pH-correct water, with the proper mineral content, when applied as an ultra-fine mist, could alleviate most dry-eye symptoms.

It seemed a natural aid for servicemembers in the deserts of Kuwait, Afghanistan and Iraq. "You can imagine how dry it is over there for our troops," Kleyne said. She donated 1,000 bottles to the troops herself and saw a jump in orders as family members bought them to resupply loved ones who asked for more. "Being in all the commissaries is exciting, and we've scheduled a huge promotion for January," she said. We're doing demonstrations in commissaries with a coupon promotion."

In addition to commissaries and the defense supply system, Nature's Tears EyeMist can be purchased at more than 30,000 drug stores and in the offices of thousands of opticians. Kleyne and her team are now developing a mist to hydrate the skin, called Nature's Mist, expected to launch in late 2004.

For any family member of our troops who would like to send Nature's Tears EyeMist, free shipping is available. When ordering, please include the servicemember's APO address. Send to www.naturestears.com



Servicemembers in Iraq "mist" each other for better eye health.

AAFES Breaks Ground at Fort Detrick

•FORT DETRICK, Md.

The Army and Air Force Exchange Service (AAFES) recently broke ground on a new $4.5-million post exchange mini-mall. The Oct. 24 ceremony was attended by many dignitaries, including AAFES Commander Maj. Gen. Kathryn Frost, USA.

Waynesboro Construction is building the mini-mall at the site of the installation's current track and field facilities across from the Main 7th St. Gate at Porter St. and Ditto Ave.

The 27,000-sq.-ft. site, slated to be completed in the spring, will include several other retail entities in addition to its main store which will accommodate seven-day-a-week shopping. These sites will include shops housing military clothing and alteration, garden, laundry and dry cleaners, barber, beauty, and Class Six. These facilities are currently scattered around the post.

A six-pump service station and a Church's Chicken outlet—with a drive-through window—will also be sited there. A large parking area will serve the facility.

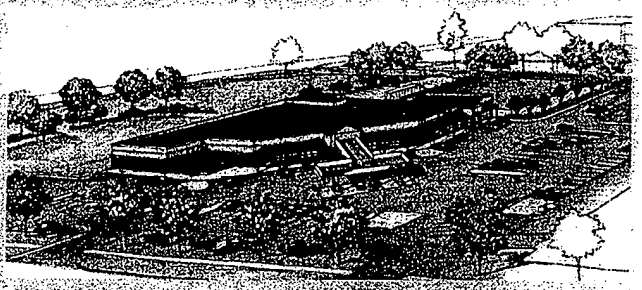
Other amenities include a snack food area. Also, a radio system for public service announcements, which is operated out of AAFES's Dallas, Texas, headquarters will be in place.

Kane Jones, manager of the AAFES facilities here, said the current facilities servicing the installation will remain open until the move to the new location.

The site is undergoing a rapid transformation into the retail hub of the base, as a Defense Commissary Agency (DeCA) commissary is set to be located across the street from the mini-mall. The groundbreaking is scheduled for the spring.



Many dignitaries, including AAFES Commander Maj. Gen. Kathryn Frost, USA (fifth from left), and Rep. Roscoe Bartlett (R-Md.) (sixth from left), were on hand for the ground breaking for a new mini-mall at Fort Detrick, Md.



Artist's rendering of the Fort Detrick, Md., mini-mall. (AAFES photos)

DeCA Eastern Region Announces Personnel Changes



Clark



Hayden

• VIRGINIA BEACH

With the Thanksgiving holiday and its accompanying shopping weekend over (*see related story on page 8*), the Eastern Region of the Defense Commissary Agency (DeCA) announced a cornucopia of store-level changes entering the last month of the calendar year.

Michael A. Dunn, previously the store director at MCAS New River, N.C., was named to the same position at Camp Lejeune, N.C. He replaced Phyllis E. Black, who was named store administrator at Fort Bragg South, N.C., replacing Gale Van Hull, who is now the store director at Fort Bragg North. Van Hull replaced Bobby W. Peters, who retired. Dunn's replacement as MCAS New River store director is John Moore, previously an intern there.

James Hayden, formerly the store administrator at RAF Lakenheath, U.K., is now store director at MCRD Parris Island, S.C., replacing Robert W. Keeth, who recently retired. Denise McAllister, who was the store administrator at NWS Charleston, S.C., was appointed store director there, replacing Hans R. Schaab, who is now deputy store director at Wiesbaden, Germany.

Paul M. Rhodes, store director at Bolling AFB, D.C., was named store director at Fort Meade, Md., replacing James E. Clark, who retired. Michael A. Auderer, previously the store director at NAB Little Creek, Va., was named store administrator, Yokota AB, Japan. Finally, George M. "Sandy" Cobb, who had been the store director at Shaw AFB, S.C., has retired. Replacements for Rhodes at Bolling AFB, Auderer at NAB Little Creek and Cobb at Shaw AFB have not yet been announced. —E&C News

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